St. Francis Hosp.

Accepted
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SHN

Trinity Health
Of New England

May 17, 2018

Susan Newton, R.N., B.S.
Supervising Nurse Consultant
Facility Licensing Investigations Section
State of Connecticut Department of Public Health

Dear Ms. Newton,

Attached is the Corrective Action Plan, in response to the violation letter dated May 3, 2018 following visits to Saint Francis Hospital and Medical Center commencing on October 16, 2017 and concluding on February 22, 2018, by representatives of the Facility Licensing and Investigations Section of the Department of Public Health.

If you have any questions related to this document, please contact me at (860) 714-1572

Thank you,

Monica Peyman

Monica Peyman, MS, NHA, CPHQ , CPPS, CJCP
Director of Quality, Patient Safety and Regulatory Affairs
St. Francis Hospital and Medical Center

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (i) General (6).

1. *Based on a tour of the hospital, a review of hospital documentation and staff interviews the hospitals governing body failed to ensure that the quality assurance improvement program reflected the complexity of multiple psychiatric units related ligature risk to ensure the well-being of patients. The finding included:
   a. Observation during tour with the Director of Nursing, the Executive Director of Nursing and the Nurse Manager of the Mount Sinai campus on 10/20/17 identified multiple ligature points throughout the psychiatric units which included a child unit, adolescent units, and adult units. Observation identified the following:
   b. Carts with monitors and game equipment located in the child/adolescent units had long electrical cords. Subsequent to the surveyors inquiry on 10/20/17, the carts with game equipment was removed and secured to a locked area.
   c. A television unit had long electrical cords located in the child/adolescent units. Subsequent to the surveyors inquiry on I0/20/17, the television was removed and secured to a locked area.
   d. The creative therapy and groups rooms for all psychiatric units had scissors, cleaning supplies, an iron and paints in the cabinets that were not locked. Further review identified that patients are escorted by staff to the room and staff are always in attendance when patients are in the creative therapy/group rooms. The Nurse Manager further indicated that keys were not available to lock the cabinets.
   e. The group rooms and creative therapy rooms on the adolescent/child units had handles on the cabinets that were potential ligature points. Subsequent to the surveyors inquiry on I0/20/17 at PM, the Director of Nursing indicated groups would be held in a common area until the risk could be mitigated.
   f. It was observed on 10/20/17 at 4:45pm that patients go off the all psychiatric units to a therapy room and use the bathroom located outside the therapy room. Further review identified that patients are escorted to the bathroom, however, the patients are in the bathroom facilities alone. The bathroom plumbing was exposed and not covered, which posed a ligature risk.
   g. A metal elbow on a door within the unit located on both 7 West and 8 West was protruding by approximately twelve inches in area that was not in constant observation by staff.

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Interview and review of the environmental rounds sheets with Nurse Manager #4 and #5 on 10/30/17 at I:00 PM dated 1/26/17 through 9/28/17 failed to identify the assessment of ligature points on all psychiatric units. Nurse Manager #4 and #5 indicated environmental assessments were conducted twice a year by a team of employees that included both clinical and facility staff members however, ligature points were not included in the risk assessment and should have been.
An alternate accreditation agency conducted an assessment of the environment in September of 2017. Interview and review of agencies findings with the Manager of Engineering on 10/31/17 at 11:30 AM indicated twenty seven areas had been identified as a ligature/safety risk on multiple psychiatric units. The Manager of Engineering identified that although some of the environmental risks that were identified by the alternate accreditation body had been corrected, others had not been completed as of 10/31/l 7.

Further interview with the Manager of Engineering identified on 10/8/17 the hospital utilized an outside consultant that conducted a comprehensive environmental assessment of the psychiatric units. Interview and review of consultant's findings with the Manager of Engineering on 10/31/17 at 12:00 PM indicated fifty eight areas in total had been identified as a ligature/safety risk on the psychiatric units. The Manager of Engineering indicated although some of the environmental risks that were identified by the consultant had been corrected, others had not been completed as of 10/31/l 7.

Interview and review of the unit quality committee minutes dated 1/6/17 through 9/14/17 with Nurse Manager #4 and #5 on 10/30/17 at 1:00 PM identified the unit quality committee met quarterly, however, failed to identify ligature risk as part of their program. Further interview with Nurse Manager #4 and #5 indicated ligature risk should have been included as a quality indicator to ensure the safety and well-being of the patients and had not been.

Interview and review of the hospital wide quality assurance program with the Director of Quality on 10/31/17 at 2:00 PM identified the psychiatric units reported to the quality assurance program annually, however, failed to report ligature risk as part of the environmental assessment, tracking and/or monitoring for safety and quality. Further interview with the Director of Quality indicated a ligature risk assessment, data collection, tracking and monitoring would be incorporated into both the unit based and hospital wide

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QAPI program.
Review of the Quality Committee responsibilities in part identified that the quality committee provided organizational-wide oversight to the quality and safety of care delivered throughout the organization. The purpose of the community was to promote high reliable, safe, high quality care and experience to each patient. The committee would be responsible to ensure specific performance improvement projects that were aligned with the organization's strategic goals, safety and quality metrics. The committee would ensure prioritization and organizational performance improvement initiatives through the use of data, address barriers to progress, review, analyze and respond to patient safety issues. Moreover, the committee would review, update, and recommend approval of the organizational annual performance improvement plan and communicate system performance improvement priorities

initiatives. Further interview with the Director of Quality on 10/31/17 at 2:15 PM identified the hospital wide quality assurance and improvement committee failed to report ligature risk related to the multiple psychiatric units to the hospital's governing body as the quality committee was not aware that the environmental risk assessment did not include an a review of ligature points.

Responses to #1:
1) Measures implemented to prevent a recurrence of each identified issue of noncompliance: Carts with monitors and game equipment were removed from the environment on October 20, 2017. The TV unit was removed from the environment on October 20, 2017. The TV unit electrical cord was shortened and then returned to service on October 23, 2017. The TV is only used with direct supervision. The creative therapy and group rooms were taken out of service and locked on October 20, 2017. Group activities are provided for patients on each unit. The bathroom outside the therapy room is locked and not in service as of October 27, 2017. The metal elbows on 7 West and 8 West were ordered on November 2, 2017. The doors were under constant observation by a staff member 24 hours a day until the new doors with ligature resistant hinges were installed on December 23, 2017.

2) Date each such corrective measure or change is effective: please see dates above.

3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained: Environmental Risk Assessments have been enhanced to comprehensively contain ligature risks since the September 2017 Joint Commission survey at St Francis Hospital and Medical Center. The Risk Assessments also include the

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recommendations surrounding identification of ligature risks from an outside consultant utilized October 3, 2017. The enhanced risk assessments are conducted at least annually and are reported out by the Behavioral Health Service Line in their annual report to the Hospital Quality Committee. Information on ligature risks in the Behavioral Health Units was reported to the hospital's governing body Quality Committee at their November 2017 meeting.

4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Nurse Executive Director, Behavioral Health.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (i) General (6).

2. *Based on a tour of the hospital, review of hospital policies, hospital documentation and staff interviews, the hospital failed to ensure that multiple psychiatric units were maintained in such a manner as to promote the safety and well-being of patients when multiple ligature points were identified. The findings include:
Observation during tour with the Director of Nursing, the Executive Director of Nursing and the Nurse Manager of the Mount Sinai campus on 10/20/17 identified multiple ligature points throughout the psychiatric units which included a child unit, adolescent units, and adult units.
Observation identified the following:
   a. Carts with monitors and game equipment located in the child/adolescent units had long electrical cords. Subsequent to the surveyors inquiry on 10/20/17, the carts with game equipment was removed and secured to a locked area.
   b. A television unit had long electrical cords located in the child/adolescent units. Subsequent to the surveyors inquiry on 10/20/17, the television was removed and secured to a locked area.
   c. The creative therapy and groups rooms for all psychiatric units had scissors, cleaning supplies, an iron and paints in the cabinets that were not locked. Further review identified that patients are escorted by staff to the room and staff are always in attendance when patients are in the creative therapy/group rooms. The Nurse Manager further indicated that keys were not available to lock the cabinets.
   d. The group rooms and creative therapy rooms on the adolescent/child units had handles on the cabinets that were potential ligature points. Subsequent to the surveyors inquiry on 10/20/17 at 5pm, the Director of Nursing indicated groups would be held in a common area until the risk could be mitigated.
   e. It was observed on 10/20/17 at 4:45pm that patients go off the all psychiatric units to a therapy room and use the bathroom located outside

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the therapy room. Further review identified that patients are escorted to the bathroom, however, the patients are in the bathroom facilities alone. The bathroom plumbing was exposed and not covered, which posed a ligature risk.

f. A metal elbow on a door within the unit located on both 7 West and 8 West was protruding by approximately twelve inches in area that was not in constant observation by staff.

Interviews with the Director of Nursing, the Executive Director of Nursing and the Nurse
Manager on 10/20/17 at 5:15pm indicated although routine environmental rounds had been conducted by the hospital, it was identified that an alternate accreditation agency conducted an assessment of the environment in September of2017 and identified the hospital's environmental assessment was not comprehensive and the assessment identified multiple ligature risks.
Subsequently, the hospital utilized a consultant who conducted a full environmental assessment on 10/8/17. Further interview with the Director of Nursing indicated that some of the environmental risks had been completed and a plan was in place to complete the rest.

Review of the 2016 psychiatric risk assessment conducted by the hospital identified cords over
three feet in length on the child/adolescent units, however observation of the cords identified that they were still present on 10/20/17.
The Department requested and received an immediate plan of correction dated 10/20/17 which identified that television carts, game equipment, and televisions that contained long electric cords would be immediately removed. The creative therapy and group room would not be used and groups would be provided in the common area. A staff member would be stationed to visualize the area where the elbow attachments were found on the doors until they could be removed. The nursing supervisor would be responsible to ensure compliance with the immediate plan of correction.

Responses to #2:
1) Measures implemented to prevent a recurrence of each identified issue of noncompliance:
Carts with monitors and game equipment were removed from the environment on October 20, 2017. The TV unit was removed from the environment on October 20, 2017. The TV unit electrical cord was shortened and then returned to service on October 23, 2017. The TV is only used with direct supervision. The creative therapy and group rooms were taken out of service and locked on October 20, 2017. Group activities are provided for patients on each unit. The bathroom outside the therapy room is locked and not in service as of October 27, 2017. The metal elbows on 7 West and 8 West were

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ordered on November 2, 2017. The doors were under constant observation by a staff member 24 hours a day until the new doors with ligature resistant hinges were installed on December 23, 2017.

2) Date each such corrective measure or change is effective: please see dates above.

3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained: Environmental Risk Assessments have been enhanced to comprehensively contain ligature risks since the September 2017 Joint Commission survey at St Francis Hospital and Medical Center. The Risk Assessments also include the recommendations surrounding identification of ligature risks from an outside consultant utilized October 3, 2017. The enhanced risk assessments are conducted at least annually and are reported out by the Behavioral Health Service Line in their annual report to the Hospital Quality Committee.

4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Nurse Executive Director, Behavioral Health.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (i) General (6).

3. *Based on tour and observations of the Emergency Department (ED) psychiatric treatment area, the hospital failed to ensure a safe environment when 4 of 7 sinks had paddle-type hot and cold water levers that posed a potential ligature point. The findings include:
   a. A tour of the ED psychiatric treatment area with the Director of the ED on 10/30/17 at 2:00 PM identified 4 sinks in the common hallway that were accessible to patients. Each sink had paddle-type hot and cold water levers that posed a potential ligature point. Although the sinks were in a common hallway with staff in the vicinity, the sinks were not being monitored by staff as a potential ligature point.

Responses to #3:
1) Measures implemented to prevent a recurrence of each identified issue of noncompliance: Ligature resistant replacement sink levers were ordered on November 1, 2017. Due to a nationwide shortage of these items and after further discussion on November 22, 2017 with the DPH Supervising Nurse Consultant, the hospital inactivated two sinks not in constant direct view 24/7 of ED staff while awaiting arrival of the approved replacement sink levers. The other two sinks are in direct view of ED staff 24/7 and were allowed to be utilized while awaiting approved replacement sink levers. The levers arrived and were installed December 12 and 13, 2017.

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2) Date each such corrective measure or change is effective: December 13, 2017.

3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained: No further monitoring required.

4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Facilities Maintenance Manager.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or *(i)* General (6).

4. *Based on clinical record review and interview for 1 (P#200) of 4 patients who received care in the

Behavioral Health area of the Emergency Department (ED) the facility failed to ensure that the patient was free from physical abuse, that the Security Officer (SO) had updated training on crisis prevention and failed to ensure that the hospital policy included guidance as to notification of local law enforcement when a crime occurred. The findings include:

a. P#200 was evaluated in the ED, medically cleared and placed in the behavioral health area of the ED for a crisis evaluation. P#200's history included antisocial personality disorder, bipolar disorder and schizophrenia. According to facility documentation P#200 was experiencing paranoid delusions. On 11/27/17 at 6:30 AM P#200 was belligerent, agitated and verbally abusive to staff. He/she was reevaluated and Geodon 20 milligrams intramuscular (used to treat Schizophrenia and the manic symptoms of bipolar disorder) was ordered.
During an interview with RN#I00 on 12/11/17 at 12:00 PM, RN#I00 indicated when he/she
first encountered P#200 he/she was verbally loud and refused to be evaluated by the physician. The physician ordered P#200 to receive an intramuscular injection (IM) of Geodon. RN#I00 called security for assistance because of P#200's behaviors. SO#10 and SO#20 responded to assist as per usual routine in that situation. RN#I00 indicated when SO#10 and SO#20 entered the room P#200 was in bed with a blanket covering his/her head. When P#200 saw SO#10, P#200 immediately jumped out of bed and became louder and stood in front of SO# IO in a "fighting stance". RN#I00 proceeded to stand behind SO#IO. RN#I00 indicated he/she was not familiar with P#200 therefore he/she consulted with SO#20 who instructed RN#I00 that P#200 was not usually assaultive and would back down when authority showed control of the situation. SO#10 removed the radios from his/her person and positioned him/herself in a "fighting stance"

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in front of P#200. SO#10 and P#200 continued to argue back and forth. RN#100 indicated he/she signaled for staff to call for assistance because the situation was continuing to escalate.
When he/she turned around RN#100 saw SO #10 lunge at P#200 and push P#200 onto the bed at which time both P#200 and SO #100 rolled off the bed onto the floor of the opposite side of the bed. P#200 was on the floor up against the bed and wall. RN#100 saw SO#10 strike P#200 in the face with a closed fist. Upon surveyor inquiry RN#100 did not recall the number of times SO#10 struck P#200 and he/she did not recall seeing P#200 strike SO#IO at any time.

During an interview with Crisis Clinician (CC) #10 on 12/11/17 at 1:00 PM he/she indicated while evaluating a patient in another room (Room 8) he/she overheard loud voices and an altercation coming from P#200's room (Room 12). CC#IO indicated SO#10 was loudly saying "Come on". "Are you going to make this day". CC#10 then proceeded to P#200's room. Upon arrival he/she saw SO#10 with his/her arms around P#200 rolling over P#200's bed to the floor on the opposite side of the bed. CC#10 indicated he/she did not see P#200 strike SO#10. CC#10 then saw SO#10 make closed fist punching gestures towards P#200. CC#IO did not see SO#IO's fist make contact with P#200. CC#10 then loudly yelled for SO#10 to stop however SO#10 continued to strike P#200 a total of 3-4 times. CC# IO indicated SO#IO stopped striking P#200 when additional emergency staff arrived within minutes.
During an interview with Security Officer (SO) #20 on 12/11/17 at 2:00 PM, he/she indicated a medical assist was called to P#200's room and SO#IO and SO#20 responded to the room.
RN#100 needed to administer medication to P#200 and he/she was threatening violence. Upon arrival, when P#200 saw SO#IO he/she immediately stood up and got into SO#IO's face yelling and cursing. At first SO#10 did not respond to P#200. SO#10 proceeded to inform P#200 that he/she needed to get back in bed. SO#10 began assisting P#200 back to bed at which time both P#200 and SO#10 rolled off the bed opposite side of the bed onto the floor. SO#20 indicated he/she did not see P#200 strike SO#10. SO#IO then proceeded to strike P#200 3-4 times in the face.
According to a written report by SO#10 dated 11/27/17 at 8:30 AM, SO#10 indicated P#200 had stood in a fighting stance in front of SO#10 with his/her fist balled up, threatening to hang and kill SO#10. SO#IO indicated he/she attempted to deescalate the situation and distance

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him/herself from P#200. Initially P#200 sat back on the bed however when RN#I00 approached P#200 with the injection P#200 stood up in RN#I00's face with a balled fist, threatening him/her. RN#IO0 ran behind SO#I0 and SO#IO instructed P#200 to lie back in bed. P#200 continued to approach SO#IO swinging his/her fist, striking SO#IO several times in the face. The report indicated SO#IO attempted to subdue P#200 by placing P#200 on the bed, while P#200 continued to strike SO#IO on the nose and right eye. SO#IO indicated in the report he/she then struck P#200 in an attempt to defended him/herself and stop P#200 from assaulting SO#IO. SO#I0 was eventually able to hold P#200's arms and stop him/her from striking SO#I0.

According to medical record documentation subsequent to the incident, P#200 was moved to the main ED for medical evaluation and treatment. P#200 suffered from a nasal bone fracture and left orbital floor fracture. His/her injuries did not require surgical intervention and P#200 was transferred to Inpatient Behavioral Health for admission.

The hospital's Patient Rights policy indicated the patient has the right to be free from mental, physical, sexual and verbal abuse, neglect and exploitation. In addition, the Employee behavior policy indicated behaviors including: fighting or assault on a patient, visitor, supplier and/or a fellow employee are prohibited.

During a review of SO#I O's employee file with the Vice President (VP) of Regulatory Readiness on 12/11/17 it was identified that SO#!0 previously had non-violent crisis prevention (CPI) training however his/her annual training had expired 4/20/16 and SO#I0 had not received his/her annual competency training for 2017.
Health Stream Patient Assault and Abuse training indicated patient abuse by a healthcare worker is a breach of medical ethics. In addition assault and abuse are crimes punishable by jail time and fines.
During a review of hospital policies (Patient Rights and Workplace Violence with the Vice President (VP) of Regulatory Readiness and the Executive Nursing Director of the ED om 12/11/17 and 12/12/17 it was identified that the policies did not address the notification of local law enforcement in the case of an alleged/witnessed assault or abuse of a patient, visitor or employee occurs. Additionally review of the hospital policies did not identify the procedure to implement should an allegation or witnessed incident of assault or abuse occur.

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Responses to #4:

1) Measures implemented to prevent a recurrence of each identified issue of noncompliance: All security staff were re-educated in Non-Violent Crisis Intervention (NVCI) by 2/28/18. Per correspondence with the contactor U. S. Security Associates, all new security officers sent to the hospital will have completed their yearly NVCI prior to their first day reporting to the hospital. The hospital's Director of Security will maintain quarterly tracking of Security Officers certification/recertification. The Director of Nursing and the Executive Director of Quality, Regulatory and Safety sent out a Safety Alert to all staff via email January 17, 2018. The Safety Alert detailed the staff to utilize the chain of command in informing their supervisor in the event of an allegation or actual assault of a patient so that Risk Management will be included in determining the next steps including reporting to law enforcement as appropriate and the patient's request.

2) Date each such corrective measure or change is effective: please see above dates.

3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained: The hospital's Director of Security will maintain quarterly tracking of Security Officers certification/recertification.

4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Director of Security.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (i) General (6).

5.)Based on clinical record review and interview for 1 (P#200) of 5 patients reviewed for the use of restraints the hospital failed to ensure restraints were applied based on an accurate physicians order. The findings include:

a. P#200 was evaluated in the ED for a crisis evaluation. P#2's history included antisocial personality disorder, bipolar disorder and schizophrenia.

A physicians order entered on 11/27/17 at 10:55 AM by Registered Nurse (RN) #100 and cosigned by Medical Doctor (MD) #100 on 11/27117 at 11:19 AM indicated an order for the use of four side rail restraints however according to progress notes and assessments on 11/27/17 at 8:30 AM P#200 was placed in bilateral double secure hard locked wrist and ankle restraints. During a review of the physician orders with the Executive Nursing Director of the ED on 12/12/17 at 9:00 AM he/she indicated the documentation of the MD order for restraints was inaccurate because side rails are not used/available in the Behavioral Health area of the ED. He/she indicated RN#IO0 must have chosen the wrong option when entered the order in the electronic medical record during the emergent incident subsequently there was no order for the restraint.

Responses to #5:

1) Measures implemented to prevent a recurrence of each identified issue

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of noncompliance:
The employee entered the wrong choice of restraint order during an emergent situation. This employee was new, and in orientation, and was verbally counseled to utilize greater attention to detail. The Emergency Department conducted an eight week audit of 100% of restraints from December 15, 2017 through February 15, 2018 and found no further identification of incorrectly ordered restraints.
2) Date each such corrective measure or change is effective: please see above dates.
3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained: The Emergency Department will continue to spot check restraint orders for accuracy and completeness.
4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Executive Director, Emergency Department.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration *(2)* and/or *(g)* Pharmacy (I) and/or *(2)* and/or *(3)* and/or (4) and/or (i) General *(6)* and/or *(I)* Infection Control.

6. Based on review of hospital monthly compounding pharmacy biological testing, consultant Industrial Hygienist/Microbiologist recommendations, hospital documentation, and interviews, the hospital failed to ensure that recommendations from a qualified pharmaceutical professional were implemented to ensure safe compounding. The findings include:
    a. Tour of the compounding area of main pharmacy and interviews with the Director of Pharmacy and Pharmacy Manager on 10/17/l 7 at 1:20 PM identified that a two inch long crack was visible in the surface of the vinyl, ante room floor, creating a potential portal for Bacteria as well as potentially creating particles that could be released into the air and accumulate on the surfaces.

    The Director of Pharmacy identified that the hospital had contracted with an Industrial Hygienist/Microbiologist on 3/15/15 to conduct biological testing of and/or provide consultation regarding the hospital's compounding pharmacies.

    Review of monthly environmental air and surface samples collected by the facility from 1/10/17 through 9/22/17 as well as email communication between the Director of Pharmacy, Pharmacy Manager and the contracted Industrial Hygienist/Microbiologist identified actionable findings with corresponding recommendations that included the following:

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Nine air samples collected on 4/5/17 identified an actionable level of growth of zero cfu of fungus and twenty six cfu of bacteria in the chemo buffer area. Significant growth of both bacteria and fungus was identified in the main pharmacy, directly outside the compounding area in the data work area. Industrial Hygienist/Microbiologist directed to increase the frequency of vacuuming the HEPA filters in the work area to monthly, increase the frequency of changing the prefilters to quarterly and change the HEPA filter annually.

Nine air samples collected on 5/17/2017 identified actionable levels of two cfu of bacteria and zero cfu of fungus in the Chemo Biosafety Cabinet (CBSC). Significant growth of both bacteria and fungus was identified in the main pharmacy data work area (near the pass through). The Industrial Hygienist/Microbiologist directed to move the chemotherapy compounding to the offsite compounding facility. Tum the CBSC off. Conduct a complete cleaning. Infection Control to evaluate plumbing work being done in the pharmacy and increase containment to a double layer. Remove carpet in the main pharmacy, data work area, remove the carpet inside of the tube station and replace with neoprene. Replace portable HEPA filter outside the cleanroom once the pharmacy work was complete. Consult with engineering regarding negative pressure in chemo buffer room. Resampling on 6/2/17, 6/9/17, and 6/23/17 did not identify actionable levels of growth. The pharmacy work area continued to grow significant amounts of bacteria and fungus. The Industrial Hygienist/Microbiologist directed to reopen the chemo buffer room on 7/11/17.

Nine air samples collected on 7/19/17 identified actionable levels of growth of thirty cfu of bacteria and one cfu of fungus in the Chemo Buffer Area and two cfu of bacteria and zero cfu fungus in the IV prep area. The chemo buffer room was completely cleaned with bleach by the pharmacy personnel and decluttered on 7/26/17. Three air samples collected on 7/26/17 identified no growth.

Nine air samples collected on 8/8/17 identified actionable levels of one hundred sixteen cfu of bacteria and thirteen cfu of fungus in the chemo buffer area; eighteen cfu of bacteria and two cfu of fungus in the anteroom. Use of chemo buffer room was suspended on 8/22/17. Retest of three air samples collected on 8/22/17 identified actionable growth of one cfu of bacteria in the chemo buffer room and two cfu of bacteria in the anteroom as well as consultation with Industrial Hygienist /Microbiologist directed carpet removal in main pharmacy as well as removing carpet from tube station and reinforcing proper cleaning

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procedures. The facility analysis identified a gap between the initial report of labs collected on 8/8/17 (8/18/17) and implementation of remediation, including suspension of use of chemo buffer room on 8/22/17. The facility remediation for the gap in reviewing the actionable levels of growth identified in the sample of 8/8/17 included adding the involvement of the Infection Preventionist #2 to review all reported results and actions in the absence of the designated pharmacy personnel. IP #2 to evaluate all patients who received chemotherapy since the date of the sample (8/8/17 through 8/22/17). On 9/11/17 FRP was installed on the walls, epoxy paint was applied, floor seams were repaired, HEPA filters replaced and the ante room was certified as ISO class 7, the hazardous drug buffer room was certified as an ISO class 7, and the non-hazardous drug buffer room was certified as an ISO class 7.

Nine air samples and surface samples were collected on 9/21/2017 identified no actionable levels of growth per Industrial Hygienist /Microbiologist. The plan was to re-open the chemo buffer room on 10/06/17.

Interview with the Industrial Hygienist /Microbiologist on 10/17/l 7 at 11:00 AM identified that, although there had been a plumbing leak in the main pharmacy, in his/her opinion, patient care had not been affected.

Additionally he/she identified that the pneumatic tube system lined with a carpet type material and positioned close to the pass through in the main pharmacy may be a source of contamination and was not on a regular maintenance program.

Interview with the Director of Pharmacy identified that although the Industrial Hygienist/Microbiologist had initially recommended removing the carpet in the data work area in front of the clean room, adjusting the pressure in the chemo room, and removing and replacing the carpeting lining the tube system in response to actionable growth identified in samples collected on 5/17/17, the carpet was not removed until 9/14/17 as removal required relocation of multiple computers and adequate IT support was not available at that time. The pressure in the chemo room was not adjusted until 8/11117 as it required and outside contractor; and the carpeting in the tube system had not yet been replaced due to concerns that replacing the carpeting with neoprene would void the current warranty. Review of the interventions for actionable growth on samples collected on 8/8/17 identified that the results and recommendations were emailed by the Industrial Hygienist on Friday, 8/18/17 to the Director of Pharmacy, however, both pharmacists were unavailable to review the results and/or implement the interventions until Tues, 8/22/17 (Use of chemo buffer room was suspended on 8/22/17) which put patients who received chemotherapy during that timeframe at risk of receiving contaminated product. The facility subsequently reviewed all patients who received chemotherapy and no infections were identified.

Responses to #6:

1) Measures implemented to prevent a recurrence of each identified issue of noncompliance:
Clarification: St Francis Hospital and Medical Center followed and implemented all of the Industrial Hygienist/Microbiologist recommendations. The two inch long crack in the surface of the vinyl, ante room floor was fixed on 10/30/17. The hospital increased the frequency of the vacuuming the HEPA

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filters and changing the filters as directed. The pneumatic tube system lined with a carpet type material was fixed by an independent contractor who works with the PEVCO system on February 5 and 6, 2018. The Industrial Hygienist/Microbiologist conducted a site visit of the St. Francis Medical Center Pharmacies on April 26, 2018 and identified the above recommendations had been fully implemented and identified no further actionable items related to the carpeting and flooring.
2) Date each such corrective measure or change is effective: please see above dates.
3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained: The Hospital continues to conduct a monthly Interdisciplinary Environmental meeting per the Industrial Hygienist/Microbiologist's recommendation, to ensure a safe compounding environment. In order to maintain a safe compounding environment;

- Environmental sampling is performed monthly.
- Surface sampling is performed every 6 months.
- The frequency of sampling may be increased based on collaboration with the consultant.
- Sampling results are reviewed by Infection Prevention monthly.

4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Director, Pharmacy Services.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (h) Dietary (I) and/or (i) General (6) and/or *(I)* Infection control.

7. Based on tour of the kitchen (a contracted service), dry storage areas and refrigerators the hospital failed to ensure that canned foods and raw meat had an identified use buy date clearly identified. The finding include:
   a. Tour of the kitchen on 10/19/17 at 9:00 AM with Registered Dietician (RD) #1 identified dry storage included large cans that were stored in a rack, tilted at an angle that allowed the cans roll forward in rotation. Inspection of the cans with RD # 1 and Store Room Clerk #1 failed to identify that the cans included an expiration and/or use by date. Dry storage also included a twenty pound bag of brown rice that was open, and not sealed, causing exposure of the rice to particles in the air, insects, and potentially compromising product freshness. Observation of a walk-in meat cooler at 10:00 AM with the Director of Contracted Service #1 identified that stacked boxes of chicken breasts were dated 9/13/17 and 8/13/17 respectively. In one box, the individually wrapped chicken breasts appeared to be frozen and in the other box, the chicken breasts appeared to be thawed. Interview with Storage Clerk #1 identified that all of the chicken breasts were utilized each day and there was no need to label the box with the date it was opened and/or the use by date and further identified that he/she assumed that the dates were when the chicken breasts were produced. Additional boxes labeled boneless beef round roasts contained multiple pieces of what appeared to be vacuumed packed, thawed, raw, beef. One package was positioned on top of the box and did not have a visible date, or label that identified a use by date. Interview with the Director of Contracted Service #1 on 10/19/17 at 11:00 AM identified that he/she was not able to comment on the safety of the food as he/she was not aware of the of the scope of the issue but, must assume that the food was not safe. Subsequent to surveyor inquiry, of 10/19/17, all unlabeled cans were set aside until use by dates could be confirmed

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with the distributor. Meat in the meat cooler without a use by date that could be confirmed was to be discarded. Staff training was initiated and completed.

Contracted Service #1 Food Safety Product Labeling and Dating Guide identified that rice should be stored in dry storage for greater than 2 years in a tightly closed container, fresh roasts should be stored in the refrigerator at 40 degrees Fahrenheit (F) for 3-5 days, and fresh chicken should be stored in the refrigerator at 40 degrees F for 1-2 days.

Responses to #7:
1) Measures implemented to prevent a recurrence of each identified issue of noncompliance:
The Director of Food and Nutrition created an action plan to immediately address the failure to ensure canned foods and raw meat had an identified use date clearly identified on each item:
On 10/19/17, all unlabeled canned items were set aside in a separate location until the distributors were contacted for available expiration/do not use dates and any items the distributor could not verify with a date were discarded and not used.
The District Regional Safety Manager inspected the facility on 10/19/17 and provided guidance on best practices.
All production and food storeroom employees were educated by 10/23/17 on best practices with regards to storing, rotating, dating and labeling and "use by date" for all products. Food service training was added to Healthstream for new hires and existing employees on an annual basis. Audits were conducted for 10 weeks (completed 1/5/18) at unannounced times for compliance with practice of use by date labeling.
On 10/19/17, there was a complete inspection conducted of the cooler – any beef or chicken products located outside of box which was not labeled with a use by date were immediately discarded and not used.
The District Regional Safety Manager inspected the facility on 10/19/17 and provided guidance on best practices.
All production and food storeroom employees were educated by 10/23/17 on best practices with regards to storing, rotating, dating and labeling and "use by date" for all beef and chicken products. Food service training was added to Healthstream for new hires and existing employees on an annual basis. Audits were conducted for 10 weeks (completed 1/5/18) at unannounced times for compliance with practice of use by date labeling.
2) Date each such corrective measure or change is effective: please see above and below dates.
3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained:
Audits were conducted for 10 weeks (completed 1/5/18) at unannounced times for compliance with practice of use by date labeling. Twice yearly monitoring of the Main Kitchen is completed by an Interdisciplinary Environmental Rounds Team which will continue to monitor compliance.
4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Director of Food and Nutrition.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (j) General (6).

8. Based on observation, review of the environment of care rounds, and

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interviews on I0/16/17 at 10:30 AM the hospital failed to ensure that the foam gaskets in the fiberglass shower stalls were properly maintained and in good repair. The findings include:

a. Tour of the surgical unit (7-7) on 10/16/17 at 11:00 AM with Infection Preventionist #2 and the Safety Program Manager identified that rooms #7736 and 7734 contained a fiberglass, walk-in shower with a fabric/plastic shower curtain. A soft, pliable appearing, raised rubber shower dam was affixed to the lower, front edge of the shower, on the floor. Approximately four inches of the dam was detached from the floor and loose, creating both a potential tripping hazard as well as creating area for potential accumulation of moisture and bacterial growth. Infection Preventionist #2 identified that the shower dams were placed to prevent water from seeping from the showers to the rest of the bathroom area which would create a slipping hazard for both patients and staff. In an email dated 10/20/17, Infection Preventionist #2 identified that six other rooms were identified with detached and/or separated shower dams. According to Infection Preventionist #2 and subsequent to surveyor inquiry, the identified separations were either replaced and or repaired and Environment Services (EVS) was reminded to report any changes in the integrity of the shower dams.

Responses to #8:

1) Measures implemented to prevent a recurrence of each identified issue of noncompliance:
The shower dam identified on 10/16/17 was reattached to the shower floor on 10/16/17. In surveying other showers on that unit on 10/20/17, the Infection Preventionist identified 6 out of the remaining 32 rooms had the same potential trip hazard. Those showers were repaired on 10/23/17.
2) Date each such corrective measure or change is effective: please see above dates.
3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained: Environmental Services employees were instructed to report any changes in the integrity of the shower dams on a regular basis. Twice yearly rounds are conducted by an Interdisciplinary Environmental Rounding Team who will continue to monitor showers in the clinical units.
4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Supervisor, Environmental Services.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical staff (2)(B) and/or (i) General (6).

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9. *Based on review of clinical records, hospital documentation, hospital policies and procedures, andinterviews for one of three patients who required a removal of by a right chest implanted port by an interventional radiologist (IR), Patient #11, the hospital failed to ensure that the IR confirmed the surgical site in accordance with professional standards of practice. The findings include:

a. Patient #11 was admitted to the hospital on 11/3/16 for Altered Mental Status (AMS). Past medical history was significant for chronic lymphocytic leukemia (currently undergoing chemotherapy) as well as automatic implantable cardiac defibrillator. Assessment and Plan included, in part, sepsis of unclear origin. The patient had a history of atrial fibrillation with a pacer and defibrillator in place as well as a history of ventricular tachycardia with a pacer and ICD in place. The port was accessed to draw blood and a sepsis protocol was initiated.
A chest x-ray dated 11/3/16 identified a pacing device and chest port, but failed to identify the location or laterality. A CT of the chest without contrast dated 11/7/16 failed to identify a pacing device or chest port. Nursing flowsheets identified a permanent pacemaker (no location/laterality identified).
A pre-procedure checklist dated 11/09/16 at 3:06 PM identified that consents were verified, radiological studies were available, correct equipment was available, and site marking was completed. Time out verified by MD #32 and PA #1 at 3:06 PM identified correct patient, correct site, site mark, correct side, correct patient position, correct procedure of port removal, consents verified, radiology studies available, correct equipment available, safety precautions reviewed, and time out verified.A Consent for Surgery signed by Patient #11 on 11/9/16 at 3:20 PM included PA #11's signature as the licensed practitioner as well as a witness signature. The consent authorized PA
#11 and MD #32 to perform a port removal. Location/laterality of the port was not identified. Although the risks of bleeding and infection were identified the unforeseeable risk of performing surgery on the wrong site was notidentified.
An interventional radiology procedure note dated 11/9/16 at 5:04 PM by Physician Assistant (PA) #1 identified that Patient #11 had a presenting diagnoses of sepsis. The procedure performed was identified as port removal (location not identified) for an indication of line
sepsis. PA #1, under the supervision of MD #32, performed the procedure under local anesthesia. According to PA #1, a right IJ (internal jugular) port was removed without difficulty. However, initially, based upon

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information obtained from the patient, PA #1 made an incision in the left chest wall over a foreign body in anticipation that the port was in that position. A pacemaker generator was encountered and the wound was closed.

Interview with RN #4 on 10/30/17 at 1:30 PM identified that he/she had been present in interventional radiology at the time of the procedure on 11/9/16. PA #1 had directed how to position and drape the patient for the procedure including laterality and site. He/she recalled that neither the consent nor the physician order included the laterality. X-rays would have been available for review along with fluoroscopy. Site marks were not being performed for port removals at that time. RN #4 identified that PA #1 performed the checks and he/she documented in the record.

A Universal Protocol Policy for site verification/marking for interventional radiology procedures will be determined at the time of the study based on intra procedural imaging and collaborative team assessments.

Responses to #9:

1) Measures implemented to prevent a recurrence of each identified issue of noncompliance: A new Interventional Radiology guideline was instituted – when a clinician (MD or PA) is removing a port they must do a spot radiograph of the patient chest to confirm exact location of the port being removed. This is done on the same procedure table, before the time out, before the incision is conducted. Communication was emailed to all IR staff members of the IR guideline and inclusion of the spot radiograph confirmation as part of the time out.

2) Date each such corrective measure or change is effective: November 15, 2016.

3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained: The Chief of Interventional radiology audited 25 port removal procedures for the presence of a spot radiograph before incision.

4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Chief of Interventional Radiology

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (e) Nursing service (l) and/or (i) General (6).

10. Based on review of clinical records, hospital documentation, policies and

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procedures and interviews for one of three patients who received care and services on an in-patient medical surgical floor, Patient #22, the hospital failed to ensure that warm drinks were served at a safe temperature to prevent bums and/or failed to update the patient's plan of care to reduce the potential of further injury. The findings include:

a. Patient #22 was admitted to an adult medical unit on 7/20/17. Diagnoses included non-ST elevated coronary artery disease and hypertension. Review of the history and physical identified that the patient presented with altered mental status and confusion, however, baseline was alert and oriented.

A Plan of Care initiated on 7/21/16 identified problems of safety risk with the goal that the patient would remain free of physical injury and neurological deficit with the goal that neurological status would remain stable or improve. Interventions included fall precautions, call bell within reach, bed alarm on, and monitor to maintain safety. The patient was described as alert to self with confused conversation but pleasant and cooperative. On 7/22/16 outcomes included safety maintained, encouraged use of call bell, frequent comfort and safety rounds and patient alert and oriented but very forgetful.

A Geriatric Medicine Consultation dated 7/21/16 at 12:08 PM identified a plan that included gentle re-orientation to surroundings, and routines and frequent safety checks.

A progress note dated 7/23/16 at 2:40 PM by RN #2 identified that at approximately 2:00 PM, Patient #22 was noted to have spilled hot coffee on his/her hospital gown. The patient's gown was changed and skin was assessed. Redness was identified on the left flank and underside of the left forearm. The patient denied pain and cool compresses were offered, but refused.
Reassessment at approximately 5:30 PM identified that redness of the left forearm was resolved and the left flank area was slightly pink. Nursing plan was to continue to assess for infection or
change in condition and information was provided to the 11:00 PM-7:00 AM RN. Documentation lacked a comprehensive body assessment, measurement and/or detailed description of affected area, and/or notification of the physician.

A progress note dated 7/24/16 at 12:15 AM by RN #3 identified that a reassessment identified two areas of partial thickness skin bum blisters. One

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blister had opened creating a partial thickness skin loss area and the second area remained reddened with a large intact blister. MD #4 was notified and multiple RN's, including a wound specialist assisted with a dressing change.

An initial comprehensive wound consultation was documented by APRN #1 on 7/25/16 at 3:35 PM that identified partial thickness skin injuries of the left buttock and lower flank. Each area was individually assessed.

Review of risk/safety care plan from 7/23/16 through discharge on 7/25/16 failed to identify interventions to reduce the potential of Patient #22 spilling hot coffee on him/herself again.

Interview and tour of the adult medical surgical unit with Nurse Manager #1 (NM) on 10/23/17 at 11:30 AM identified that on 7/23/16, Patient #22, who was reclining in bed, had requested a lunch tray that was delivered without coffee. Patient #22 requested that RN #5, a new RN on orientation, provide some coffee. RN #5 prepared coffee in the staff lounge using water from the hot water dispenser in the sink in the lounge and a foam cup. RN #5 instructed the patient to let the coffee cool off, as it was hot and did not place a lid on the cup to facilitate cooling. RN #5 placed the bedside table across the bed in front of Patient #22, pulled out the lower tray, and placed the open cup on the tray. According to NM#!; RN #2 and RN #5 heard Patient #22 call out, entered the room and found that the coffee had spilled on the patient. NM # 1 further identified that the sink in the staff lounge on the unit contained a hot water dispenser that was previously set by engineering at 190 degrees Fahrenheit (F). Since the occurrence with Patient #22, all hot water dispensers and hot water controls accessible for patient use have been recalibrated to dispense water at a maximum temperature of 150 degrees F. and access to the hot water temperature controls has been locked out for use by engineering personnel only.

Responses to #10:

1) Measures implemented to prevent a recurrence of each identified issue of noncompliance:
Engineering adjusted all in-sink heated water dispensers to 150 degrees Fahrenheit in accordance with Food and Nutrition guidelines which was completed by 8/31/2016.
Styrofoam cups no longer utilized by staff for hot liquids; replaced with hot liquid paper cups with protective sleeves.
Re-education of all RNs regarding Scald Injury Prevention: "Keeping our Patients Safe from Burns Associated With Hot Liquids" via read and sign e-mail to be completed by 9/16/16.
Education regarding Scald Injury Prevention was presented at Safety Coach meeting in September 2016.
2) Date each such corrective measure or change is effective: See above dates.
3) Plan to monitor its quality assessment and performance improvement functions to ensure that the

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corrective measure or systemic change is sustained: Engineering only can adjust all in-sink heated water dispensers and periodically verifies temperature of no more than 150 degrees Fahrenheit in accordance with Food and Nutrition guidelines.
4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Directors of Nursing

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (e) Nursing service (1) and/or General (6).

11. Based on a review of the medical record review, review of facility documentation, review of facility policy and interview for one patient who expressed a concern with care (Patient #21), the facility failed to ensure that care was provided in a manner to promote patient dignity and/or in accordance with facility policy. The findings include:
    a. Patient #21 had spinal surgery at the facility on 9/12/16. Nursing narratives by RN #7 dated
    9/12/16 at 7:18 AM identified that Patient #21's urinary catheter was removed at 6:45 PM due to complaints of burning irritation. Review of facility documentation indicated that on 9/13/16 at approximately 7:00 AM, Patient #21 expressed concern that RN #7 did not wear gloves when removing the urinary catheter and/or applied cream to the perineal area on 9/12/16. Interview with Manager #8 on 11/2/17 at 2:43 PM noted that the Patient questioned why RN #7 had not worn gloves when he removed the urinary catheter and when he applied lotion to Patient #21's peri area. Review of facility documentation dated 9/15/16 identified that RN #7 reported that he had used gloves when he removed Patient #21's urinary catheter (Patient in bed) and when he applied lotion to the Patient's peri area (in the bathroom). Interview with RN #7 on 11/6/17 at 10:50 AM noted that he was in a hurry the evening of 9/12/16, did not see irritation when he examined the Patient's peri area and examined the patient without gloves. He further indicated that he wore one glove to remove Patient #21's urinary catheter and did not recall applying lotion to the Patient's peri area in the bathroom. On 11/8/17 at 11:45 AM, RN #7 identified that he would like to clarify his prior statement after reading what he had written immediately following the event. During the interview on 11/8/17, RN #7 indicated that he wore two gloves to remove the catheter when the Patient was in bed. RN #7 further clarified that he applied barrier cream to the Patient's peri area with one gloved hand while the Patient stood up in the bathroom. Interview with Patient #21 on 11/8/17 at 12:00 PM identified that he/she was I00% sure that RN #7 had not worn gloves to

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remove the catheter or apply the lotion and was more uncomfortable that he had not worn gloves to apply lotion to his/her entire peri area. He/she further noted that the intent for reporting the incident was not to get anyone fired but, to ensure that this practice did not reoccur. Although the facility investigation concluded that sexual abuse/assault could not be substantiated, it was determined that RN #7 did not follow proper nursing procedures in the care delivery process and was no longer employed by the facility.

The facility patient rights policy identified that the patient had the right to receive care in a safe setting that preserves dignity and contributes to a positiveself-image.

Further review of facility investigation dated 9/15/16 identified that RN #7 reported that he had used gloves when he removed Patient #21's urinary catheter and when he applied lotion (Critic-Aid) to the Patient's peri area. Interview with Manager #8 on 11/2/17 at 2:43 PM noted that it was not appropriate to apply lotion to Patient #21's peri area. The facility standard precaution policy directed to wear gloves when there is the potential for contact with blood, body fluids, secretions and mucous membranes. Review of the Critic Aid product insert identified Critic Aid as a moisture barrier and protects against incontinence skin maceration. The facility skin integrity policy identified moisture barrier (Critic-Aid) as an intervention to manage moisture and did not identify Critic Aid as a treatment for burning irritation.

Responses to #11:

1) Measures implemented to prevent a recurrence of each identified issue of noncompliance: The Nurse Manager conducted an in-depth investigation of this case with her staff and with patient #21. It was determined that the nurse did not follow proper nursing procedures in the care delivery process with this patient and the nurse had chosen to resign and is no longer employed in the hospital. In discussing the procedure of peri care with other staff members, all staff identified to the manager that they utilize gloves when removing a Foley catheter and utilize Critic-Aid for a moisture barrier only. The Nurse Manager talked by phone with the patient two times after the patient was discharged from the hospital. Again, the patient identified she did not want to lodge a complaint. The Nurse Manager realized that s/he did not document the discussions with the patient in the patient record and will do so in the future.

2) Date each such corrective measure or change is effective: Sept. 15, 2016

3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained: Risk Management

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completes investigations of a patient's allegation of inappropriate care and/or complaints. Risk Management will review future records for presence of the manager's note of discussions with patients regarding their allegation.

4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Director, Risk Management.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (d) Medical Records (3) and/or (e) Nursing service (l) and/or (i) General (6).

12. Based on a review of the medical record, review of facility documentation, review of facility policies and interviews for one patient (Patient #21) reviewed for complaints of care and/or mistreatment, the facility failed to ensure that the complaint and/or an assessment of the Patient was documented in the Patient's record as per policy. The finding includes:
    a. Patient #21 had spinal surgery at the facility on 9/12/16. Nursing narratives by RN #7 dated 9/12/16 at 7:18 AM identified that Patient #21's urinary catheter was removed at 6:45 PM due to complaints of burning irritation. The facility event report dated 9/20/16 indicated that Patient #21 questioned if nurses were required to use gloves to remove urinary catheters and expressed feeling uncomfortable when RN #7 did not wear gloves to remove his/her catheter when he applied lotion to his/her peri area. Review of the Patient's electronic medical record with Epic Analyst #I on 11/6/17 at 2:30 PM noted that the Patient's care concern and/or reported uncomfortable response to the care was not documented. The facility policy for unanticipated occurrences identified an unanticipated occurrence as any unusual event or circumstance that is not consistent with the routine operation of the hospital or its staff. The policy further directed that the healthcare professional involved with the patient record, in part, what took place, the patient's condition, and any actions taken.

Responses to #12:

1) Measures implemented to prevent a recurrence of each identified issue of noncompliance: The Nurse Manager conducted an in-depth investigation of this case with her staff and with patient #21. The patient repeatedly identified this was not a complaint.. The Nurse Manager talked by phone with the patient two times after the patient was discharged from the hospital. Again, the patient identified she did not want to lodge a complaint. The Nurse Manager realized that s/he did not document the discussions with the patient in the patient record and will do so in the future.

2) Date each such corrective measure or change is effective: Sept. 15, 2016.

3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained: Risk Management completes investigations of a patient's allegation of inappropriate care and/or complaints. Risk Management will review future

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4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Director, Risk Management.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical staff (2) and/or (d) Medical Records (3) and/or (e) Nursing service (l).

13. *Based on medical record review, review of facility documentation, review of facility policies and interviews for two of four patients (Patient #20 and #57) reviewed for nutritional intake in the ED the facility failed to address the patient's nutritional needs and/or ensure that physician's order was in place to direct nutrition provided. The finding includes:
    a. Patient #20 was admitted to the ED on 6/23/17 at 1:55 PM as a triage level 2 (emergent) with a chief complaint of hypertension. The physician assessment dated 6/23/17 indicated that the Patient was alert, oriented and abdomen was soft and non-distended. Physician orders dated 6/23/17 at 4:52 directed the administration of Norvasc (antihypertensive medication) tablet 10mg by mouth. The patient care timeline dated 6/23/17 indicated that the Norvasc was administered by mouth as ordered at 5:15 PM. Physician progress notes dated 6/23/17 at 8:39 PM indicated that the ED staff had been paging the hospitalist for the past two hours to admit the patient. Patient #20 was subsequently admitted to the 10-9 *unit* on 6/23/17 at 11:35 PM (9.5 hours in ED). Although the Patient's symptoms did not include nausea, and ordered testing did not direct that the patient not have anything by mouth, physician orders did not include dietary orders. Physician orders dated 6/24/17 at 1:11 AM directed a regular diet. Documentation by Person #4 dated 6/24/17 identified that Patient #20's treatment in the ED was despicable and unprofessional and that this included the lack of food and oral fluids for over 9 hours in the ED. Interview with Director #1 on 11/2/17 noted that if a patient asked for food or fluids, staff would inform the ED physician and the physician would make the decision. Interview with Manager #7 on 11/2/17 at 1:21 PM indicated that she did not know why the patient was not provided nutrition in the ED as she was able to take oral medication without difficulty. Manager #7 further noted that she spoke with Patient #20 on 6/24/17, the lack of food and fluids in the ED was discussed and had informed the Patient that this was unacceptable.
    b. Patient (P) #57 was evaluated in the Emergency Department (ED) on 6/16/17 for alcohol intoxication and a request for alcohol detoxification. P#57 had a history of schizophrenia, bipolar disorder, chronic obstructive pulmonary disease (COPD), diabetes mellitus Type 2

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and alcohol use. According to a progress note dated 6/16/17 at 4:38 PM, while in the behavioral Health ED P#57 was provided with a meal tray containing a sandwich. A subsequent progress note dated 6/16/17 at 11:56 PM indicated P#57 had been yelling and was noted to have an altered level of consciousness and upon assessment he/she was noted to have a pocketed piece of chewed sandwich in his/her mouth. Assessment identified P#57 with cough, expiratory wheeze, labored respirations and upper airway congestion caused by an exacerbation of his/her COPD. According to the progress note P#57 did not exhibit signs of choking/aspiration at that time. P#57 was moved to the main ED for medical evaluation and treatment. During a review of the medical record with Nurse Manager #7 on 11/2/17 at 9:00 AM it was identified that the medical record lacked a physician's order for a regular oral (PO) diet prior to P#57 receiving a sandwich.During an interview with Safety and Regulatory Compliance Specialist # 1 on 11/2/17 at 1:30 PM he/she indicated the Hospital did not have a specific policy relative to the provision of diet according to physician orders however the standard of practice would be to not administer anything orally until the patient is cleared medically, which would be evident by either a written or verbal order from a physician.

Responses to #13:
1) Measures implemented to prevent a recurrence of each identified issue of noncompliance: The need for a clinician diet order before feeding all ED patients was discussed at ED shift Safety Huddles startingNovember 2, 2017. The Food and Nutrition order for a delivery of a food tray to the ED is now hard wired – trays cannot be delivered without the presence of a diet order in the EMR.
2) Date each such corrective measure or change is effective: November 2, 2017.
3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained: Random, unannounced spots checks of the presence of a diet order before providing nourishments to patients was conducted by ED leadership throughout November and found 100% compliance.
4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Executive Director, Emergency Services.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical staff (2) and/or (e) Nursing service (I) and/or (i) General (6).

14. Based on medical record review, review of facility documentation, review of facility policies and interviews for one of three ED patients who required cardiac monitoring (Patient #24), the facility failed to ensure timely transport

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back to the ED for continuation of monitoring. The finding includes: Patient #24 was admitted to the ED as a triage level 2 (emergent) on 7/21/17 at 5:05 PM with a chief complaint of chest pain. Physician orders dated 7/21/17 directed cardiac monitoring while in the ED and may remove cardiac monitoring for testing. ED physician orders also directed a CT angiogram of the chest which was completed by 9:05 PM and results identified pulmonary embolism within all lobes of the lung. Physician orders dated 7/21/17 at 10:33 PM directed venous duplex ultrasound of bilateral lower extremities. Facility documentation indicated that the Patient's ultrasound was completed in the ultrasound department and the Patient was placed in the system at 11:26 PM for transport back to the ED. The facility documentation further identified that the Patient had not been transported back to the ED as of 11:52 PM, the transport status was escalated and the Patient returned to the ED at 1:02 AM on 7/22/17. Facility documentation dated 7/21/17 noted that the patient felt humiliated, abused and distressed regarding the care that was provided in the ED on 7/21/17 to include, in part, being left in the hall outside of the ultrasound room unattended and without monitoring or treatment. Facility documentation of response to Patient #24 dated 8/3/17 identified that the delay regarding the return from ultrasound was unfortunate. Interview with the Regulatory Specialist on 11/2/17 at 10:37 AM noted that the ED was extremely busy on 7/21/17, 2 transport staff were working as per usual and the Administrative Supervisor directed and prioritized transports. Although Patient #24 had been diagnosed with pulmonary emboli, Patient #24 was without the benefit of staff and/or cardiac monitoring for 1 hour and 36 minutes in a hallway while awaiting return to the ED. The facility patient rights policy identified a right to receive care in a safe setting that preserves dignity. The policy further identified a right to expect that the hospital will give the necessary health services to the best of its ability.

Responses to #14:

1) Measures implemented to prevent a recurrence of each identified issue of noncompliance.

The Manager of the Transportation Department discussed this incident with the transportation staff at the shift meetings the week of November 2, 2017 to ensure staff were following the Chain of Command Policy when they need assistance in times of high patient flow and transports.

2) Date each such corrective measure or change is effective: November 2, 2017.

3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained: All calls for transport are logged into an electronic system and the Manager of the Transport

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Department continues to monitor for trends and needs for adjustment in staffing for improvement in patient flow.

4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Transportation Manager

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (d) Medical Records (3) and/or (e) Nursing service[]).

15. Based on medical record review, review of facility policies and interviews for one of six patients who had a diagnosis of hypertension (Patient #24), the facility failed to notify the physician of worsening vital signs and/or follow the physician's order for medication administration. The finding includes:

a. Patient #24 was admitted with hypertensive emergency on 8/11/17 and the Patient received oral doses of Bystolic and Lisinopril on 8/12/17 at 9:45 AM as ordered. The Patient's BP was 178/98 on 8/12/13 at 5PM and MD #27 ordered oral Amlodipine 5mg at 7:35 PM. The Patient's BP increased to 204/119 at 7:56 PM, was 197/102 at 8:02 PM and the Amlodipine was administered orally at 8:04 PM. Physician notification of the increased BPs of 204/119 and 197/102 was not documented. Interview with MD #26 at 9:32 AM identified that he/she began work at 7:00 PM on 8/12/13 and if he was made aware of the elevated BPs taken at 7:56 PM and 8:02 PM he would have ordered an IV antihypertensive medication to be administered for a SBP of 200 or above in addition to the oral Amlodipine. The facility job description for Staff RN II identified an expectation for the RN to communicate clearly and effectively to appropriate persons relevant data.

b. Patient #24 had a CTA of the chest on 8/12/17 at approximately 10:04 PM. Nursing narratives dated 8/12/17 identified that the Patient returned from the CTA of the chest, SBP (systolic blood pressure) range wasl90's-200's and MD #26 was notified. Hydralazine 10 mg IV once and every 4 hours as needed for SBP > 160 was ordered by MD #26 and was administered by RN #10 at 10:22 PM. Although the Patient's SBP was documented as 185 at 6:17 AM on 8/13/17, 196 at 9:00 AM and 165 at 9:56 AM, another dose of Hydralazine was not administered and/or a reason for withholding the Hydralazine was not documented. Interview with MD #26 on 11/22/17 at 9:32 AM noted that the order for Hydralazine every four hours was not discontinued until 8/13/17 at 8:23 PM and in collaboration with nursing, nursing knows when to administer the medication and gives the medication. The facility policy for documentation of the nursing process and care

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identified that the patient record will include the documentation of care delivered and implementation of the plan. (i.e. MD orders).

Responses to #15:

1) Measures implemented to prevent a recurrence of each identified issue of noncompliance:
Staff RN counseled by manager on 8/14/2017 regarding a change in condition, the use of the Rapid Response protocol, vital sign monitoring and the need to administer medications according to physician order. Policy reviewed with all staff on unit via a read and sign.

2) Date each such corrective measure or change is effective: see dates above and below.

3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained: Auditing of 10 charts per week for prn medication administration and parameters observed will occur for 8 weeks starting May 14th, 2018 until July 14th 2018.

4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Nursing Manager 9-9

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical staff (2) and/or (d) Medical Records (3) and/or (e) Nursing service (1).

16. Based on medical record review and interviews for one of six patients who had a reported change in condition (Patient #24), the facility failed to ensure that an assessment of the Patient was documented following the change. The finding includes:
    a. Patient #24 was admitted with hypertensive emergency on 8/11/17. The Patient's BP on 8/12/17 ranged from 150/88 to 204/119 from 5:00 AM to 8:02 PM and the Patient received medications for anticoagulation and hypertension as ordered. Nursing narratives dated 8/12/17 identified that the Patient returned from the CTA of the chest, the Patient's SBP (systolic blood pressure) range was l 90's-200's and MD #26 was notified. Hydralazine 10mg IV every 4 hours as needed for SBP > 160 was ordered by MD #26 and was administered by RN #10 at 10:22 PM. The nursing note and/or flow sheet dated 8/13/17 by RN #10 indicated that the Patient's BP dropped to 177/90 post IV Hydralazine administration and the Patient complained of pleuritic pain and seeing "black spots". Although the nursing narratives further identified that MD #26 was at the bedside (per patient request), please see doctor's note, an assessment/note by MD #26 was not documented. Interview with MD #26 on 11/22/17 at 9:32 AM identified that he assessed the Patient on 8/12/17 when the Patient complained of pleuritic pain and visual "black spots" and would have documented an

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assessment if the patient had an extreme drop in BP. An assessment for the change in condition for the Patient's decrease vision was not addressed until 8/13/17 upon Patient discharge to include a stated improvement in vision and patient preference to follow-up with an ophthalmologist. Although the facility had a policy for "rapid response" the facility did not have a policy for change in condition.

Responses to #16:
1) Measures implemented to prevent a recurrence of each identified issue of noncompliance:
Individual physician mentoring completed at the time of the incident, November 22, 2017 and reinforced on May 11th 2018.
2) Date each such corrective measure or change is effective: November 22, 2017
3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained: The specific expectations related to the documentation of a new physical complaint/finding will be discussed for 4 weeks at Hospitalist's staff meetings, as well as an e-mail detailing the policy and specific responses will be sent to all Hospitalists.
4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Section Chief of Hospitalist Medicine.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b)
Administration (2) and/or (c) Medical staff (2)(8) and/or (d) Medical Records (3) and/or (e) Nursing service(]) and/or *(i)* General (6).

17. Based on a clinical record review, staff interviews and a review of the hospital's policies and procedures for one of three sampled patients (Patient #17), the hospital failed ensure the physician's orders that directed the application of restraints was complete in accordance with the hospitals policy and procedure. The findings included:
    a. Review of the clinical record identified Patient #17 was admitted to the hospital on 2/4/17 for a medical evaluation after sustaining a fall at home. Patient #17 had a diagnosis that included Alzheimer's dementia and bladder cancer. After a medical workup it was felt the fall was likely secondary to weakness in the setting of an acute respiratory illness superimposed on a baseline decreased functional capacity. Patient #17 suffered from acute hypoxic respiratory failure as a consequence of influenza and post viral pneumonia versus aspiration pneumonia. The patient completed a course of antibiotics, Tamiflu, steroids and was provided respiratory support. Patient #17 was discharged to a skilled nursing facility for rehabilitation on 2/10/17. Interview and review of the clinical record with Nurse Manager#10 on 10/31/17 at 2:00 PM identified physician's order dated 2/7/17 at 10:46 PM directed the application of soft

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restraints due to continuous successful attempts at removing hospital equipment. The physician's order failed to identify which limbs would be restrained. The nursing flow sheet indicated the right and left wrists were restrained. Wrist restraints were discontinued on 2/8/17 at I 0:30 AM. Nurse Manager #1O indicated the physician's order was not complete and should have been. The hospital policy entitled Restraints directed in part that orders for the use of restraints are to include the date, time of order, and behaviors of the patient, type of restraints and duration of the order.

Responses to #17:
1) Measures implemented to prevent a recurrence of each identified issue of noncompliance: All staff educated by Healthstream related to policy, monitoring and documentation and orders assigned on 8/29/17.
2) Date each such corrective measure or change is effective: please see dates above and below.
3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained: Restraints audited weekly for 10 weeks from November 12, 2017 to January 20, 2018 to ensure orders include necessary requirements of the physician orders.
4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Directors of Nursing

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical staff(4)(A) and/or (d) Medical Records (3).

18. *Based on a review of clinical records, review of facility documentation, and interviews, for 2 of 3 patients reviewed for insertion of nasogastric tubes (Patient #2 and 33), the hospital failed to ensure proper placement of feeding tubes and/or verification of placement prior to the use of the feeding tube and/or that the clinical record was complete/accurate. The findings include:
    a. Patient #2 presented to the ED on 9/10/16 with a two day history of increased coughing, sputum production with a question of aspiration. The patient had a history in part of a stroke, Parkinson's disease, atrial-fibrillation, and dementia. Review of the clinical record identified that the patient had a modified barium swallow (MBS) test on 9/12/16 that demonstrated silent aspiration. Review of MD #3's (Resident, Post Graduate Year 2) note dated 9/13/16 at 2:01 pm reflected that MBS complete, confirmed to have significant degrees of both silent and obvious aspiration of both pureed foods and all liquids. The plan included nothing by mouth and discuss the insertion of a percutaneous gastrostomy tube (PEG) with the family.

A nurse's note dated 9/14/16 at 2:00 pm indicated that the dobhoff tube was placed by the

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medical resident, a chest x-ray was obtained and viewed by the physician. The patient was complaining of chest pain, was short of breath, gurgling, and very anxious, a STAT EKG was ordered and completed. Morphine was ordered and administered for comfort.
Review of MD #31's (Interventional Radiologist) note dated 9/14/16 at 3:16 pm identified that the patient presented to interventional radiology (IR) for placement of a gastrostomy tube. The procedure note reflected that the dobhofftube that was placed on the floor was coiled in the chest with high suspicion for lung puncture, the procedure was aborted, and the patient was taken immediately for CT scan. MD #31 further noted that the CT of the chest demonstrated a small pneumothorax with increased right pleural effusion, the patient was experiencing desaturations in vital signs and an emergent chest tube was indicated. Subsequently a drainage catheter was placed into the right chest and the patient was transferred to the recovery room.
Review of MD #3's significant event note dated 9/15/16 at 7:27 am identified that at approximately 2 pm yesterday (9/14/16), a dobhoff tube insertion was attempted in order to facilitate PEG tube placement later in the afternoon as instructed by the interventional radiologist for insufflation of the stomach. MD #3 described the insertion of the tube to be moderately difficult as the patient was unable to hold still, however, the tube was able to be inserted with relative ease. Initially after placement, the patient coughed for approximately 30 seconds to one minute. A STAT KUB was ordered after procedure to verify placement within the GI tract. The KUB was performed and imaging briefly reviewed. The tube position was ambiguous with no radiology final read at this time. The patient was taken down to interventional radiology for PEG insertion. MD #3 further identified that he was called by IR to convey doubt about the positioning of the tube at approximately 3 pm. At that time, the tube was visualized in the right lung field and removed. A STAT CT of the chest demonstrated a small ride-sided pneumothorax as well as large bilateral pleural effusions with subsequent insertion of a chest tube.
Record review and interview with MD #3 on 10/24/17 at IO am identified that insertion of the dobhofftube was not easy related to the patient's dementia, the tube went in smoothly initially and when the tube hit the back of the patient's throat s/he began to cough and he was only able to advance the tube to about 65 centimeters. MD #3 stated the only way to confirm placement was with an x-ray and although a KUB was ordered, it was not done. MD #3 stated that the patient went to IR before the x-ray was completed so he asked IR staff to confirm placement of the tube.
Interview with the Chief Quality Officer on 10/17/17 at 2 pm stated that Residents no longer place feeding tubes on the floors.
Review of the clinical record failed to reflect that MD #3 appropriately inserted the dobhoff tube resulting in a pneumothorax, failed to document a note at the time of tube placement and/or when the patient exhibited chest pain and a change in condition.

b. Patient #33 was admitted on 9/27/17 with a history of squamous cell carcinoma of the uvula with hepatic metastasis, diabetes, and hypertension. The patient presented secondary to an elevated calcium (14.1) and decline in appetite. The clinical record indicated that on

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10/3/17 the patent was noted to be lethargic with an elevated ammonia level, was transferred to the ICU and subsequently intubated. On 10/4/17, an orogastric tube (OG) was inserted for enteral feeding/medication administration. Review of the chest x-ray dated 10/4/17 at 11:07 pm noted suboptimal positioning of the nasogastric tube with its tip seen at the level of the medial part of the left hemidiaphragm. Correlation recommended. It should be further advanced by at least 10 cm for ideal positioning. The chest x-ray dated 10/5/17 at 4:45 pm noted that the NG tube was in at least the midbody of the stomach.
A physician's note dated 10/9/17 at 2:15 pm identified that a nasogastric (dobhoff) tube was placed uneventfully with the use ofCorTrak guidance. Review of the chest x-ray report dated 10/9/17 at 12:21 pm noted that the enteric tube terminates in the distal stomach.Although the purpose of the x-ray was to verify placement of the nasogastric tube, the report failed to note the presence of the orogastric tube.
Review of the clinical record dated 10/9/17 identified that enteral feedings were initiated at 8 pm in accordance with the physician's order.
A physician's note dated 10/10/17 at 1:45 am reflected that the medicine team was notified by the RN that the patient had increased secretions with oxygen desaturations to 90%, the RN identified that the change in respiratory status was noted since the patient was started on dobhoff feedings (2 hours prior). Tube feedings were placed on hold and a STAT chest x-ray was obtained that indicated the NG tube was in the right lung. The note indicated the x-ray obtained on 10/9/17 after NGT placement verified that the tube was in the distal stomach however it appeared the comment was pertaining to the pre-existing orogastric tube.
Record review and interview with MD #28 on 10/26/17 at 9:20 am stated that the initial radiology report didn't identify that the patient had two tubes (orogastric and dobhoft) and the lower part of the lung was not visualized on initial chest x-ray. Subsequent to this incident, abdominal and chest x-rays are done to verify placement.
Response to #18:
1) Measures implemented to prevent a recurrence of each identified issue of noncompliance: Reeducation of Medical Residents on tube placement and placement complications in the simulation lab completed by 11/14/16. Hospital wide education for clinical providers, who are responsible for placing tubes, with a focus on proper placement and potential complications to be completed by 11/14/2016. Reeducation of all physicians regarding documentation of procedures per graduate Medical Education Resident Supervision Policy, Medical Staff Bylaws Article III Operative Reports 3.9, and the reporting of unanticipated outcomes completed by 11/14/16.
2) Date each such corrective measure or change is effective: 11/14/16.
3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained: The Safety Event Committee reviews all occurrences of unanticipated outcomes.
4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Chair of Medicine/CMO and Director of Educational Programs.

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The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing service(]).

19. Based on a review of clinical records, interview and policy review for 1 of 3 patients in the ICU, (Patient #4), the hospital failed to ensure the clinical record was complete. The finding includes the following:

a. Patient #4 was admitted to the facility on 3/31/17 with ongoing diarrhea, weight loss, vomiting and numbness and tingling from shoulders to feet. The physician note dated 4/2/17 at 6:12 AM indicated that the patient was found unresponsive in ventricular fibrillation and CPR was initiated, the patient was intubated and subsequently transferred to the ICU. Review of the clinical record dated 4/9/17 identified that the physician removed the patient's femoral catheter. Record review and interview with RN #1 on 10/26/17 at 10:00 AM indicated that he was present for the line removal and when he went back to check on the patient approximately 5-10 minutes later, the patient had bleeding from the catheter site requiring pressure application. RN #1 stated that although he applied pressure and notified the MD, he failed to document the incident in the record. The facility policy for documentation of the nursing process and care identified that the patient record will include documentation of care delivered and implementation of the plan.

Responses to #19:

1) Measures implemented to prevent a recurrence of each identified issue of noncompliance: Individual RN was coached during a meeting with the Nurse Manager, Nurse Director and Human Resources on 4/11/17 regarding the patient's change in status. Further clarification regarding gaps in care with RN related to documentation occurred on 4/14/17.

2) Date each such corrective measure or change is effective: 4/11/17.

3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained. E-mail sent on 11/22/17 to all Nursing staff on unit related to documentation of line removal and complications

4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Manager, MSICU.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing service (1).

20. Based on clinical record review, interview and policy review the facility failed to ensure that one patient who required peritoneal dialysis (Patient #34), the hospital failed to ensure that the patient's peritoneal dialysis was connected appropriately. The finding includes the following:

a. Patient #34 was admitted on 5/30/17 with a chronic non-healing right heel wound and was started on Augmentin. The patient had a history of end stage renal disease and administered peritoneal dialysis at home. A physician note dated 5/30/17 at 5:55 PM indicated that the patient had a Baxter adapter with him/her and that CAPD was ordered to

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include, dextrose 1.5 % in 2500 ml five times a day utilizing the cycler. Review of the dialysis flow sheets reflected that exchanges were started on 5/30/17 at approximately 8:00 PM. Review of a physician's note dated 5/31/17 identified that the night RN attached the Baxter set to the Fresenius Catheter, and was not able to use the universal adaptor. The note further indicated that the physician removed the Baxter set and attached the universal adaptor. The physician note dated 5/31/17 at 2:11 PM indicated that the patient was at some risk for peritonitis given the fact that the peritoneal set up was not done properly and that the patient would be given intraperitoneal antibiotics. The record failed to reflect a note by the RN on 5/30/17 who connected the patient to reflect that the systems were connected and/or that there was a problem with the universal adaptor. Review of the chart with the Nurse Manager on 10/26/17 stated that she reviewed the case with the RN who indicated that a piece of the adaptor was missing. Interview with Person #6 on 11/7/17 at 10:00 AM stated that the patient's one piece extension tubing was brought in from home and left at the bedside table for staff to use as the hospital uses Baxter products and the patient had a Fresenius catheter. Review of the peritoneal dialysis policy directed staff to note the type of tenckoff catheter and apply a Fresenius stay safe luer lock adaptor if needed.

Responses to #20:
1) Measures implemented to prevent a recurrence of each identified issue of noncompliance: Nurse Manager reviewed and counseled the nurse on 5/31/17 regarding proper connection for the dialysis catheter. Review of chain of command for questions reinforced as a safety behavior in the organization. Notification sent to all RN staff on unit regarding the policy for proper connection of a dialysis catheter.
2) Date each such corrective measure or change is effective: 5/31/2017
3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained. Audits of peritoneal dialysis connections Dec. 2017-April 2018 produced one case, which indicated no issues with connection.
4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Nurse Manager 4-2.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or {d) Medical Records (3). and/or (e) Nursing service(1).

21. *Based on clinical record review, interview and policy review, for one of two patients on a medical unit with suicidal ideation (Patient #60), the facility

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failed to develop a comprehensive plan of care to address suicide risk. The finding includes the following:

a. Patient #60 was admitted to the facility on 12/13/17 after jumping from an overpass and suffering numerous fractures. The patient had a history of previous suicide attempts. The patient was admitted to the intensive care unit and placed on suicide precautions with one to one (1:1) continuous observation. On 12/19/17, the patient was transferred to a surgical unit for continued care. Review of clinical record indicated that the patient was maintained on constant observation until discontinued by psychiatry on 1/17/18. Review of the record during the period of 1/17/l 7 through 2/7/18 identified that the patient did not demonstrate any self-harm behaviors and denied that s/he would harm herself while in the hospital.

A nurse's note dated 2/8/18 identified that the RN performed routine patient rounding at approximately 3:30am. The patient was found sleeping at this time with the bed alarm activated. The certified nursing assistant (CNA) was in the patient room at approximately 3:45 am to do vital signs and gave the patient a bedpan per request. Pt requested the door to the room be left cracked open. The RN checked on the patient about 4:15 am and she appeared to be sleeping. The RN re-entered patient's room at approximately 6:45 am (2 ½ hours later) and found the patient hanging by his/her neck from red shower wire and IV tubing. The patient was unable to be resuscitated and was pronounced at 6:55 am.

Review of the front page of the clinical record with the Manager on 2/22/18 at 10:00 am reflected that the patient was on "suicide precautions".

Interviews with CNA #101 on 2/23/18 at 8:55 am and CNA #100 on 2/23/18 at 8:35 am, who cared for the patient, stated the patient was on suicide precautions, however, once the constant sitter was discontinued, CNA's round every two hours and the RN's round every two hours so the patient is seen hourly. Review of the clinical record during the period of 12/13/17 through 2/8/18 with Nurse Manager #12 on 2/22/18 at 10:00 am failed to reflect that a care plan was developed to address the patient's suicide risk including but not limited to interventions following the removal of the constant observation. Further interview with the Manager identified that staff round on the patients hourly during the day and evening shift and every two hours on the night shift (11 pm- 7 am).

Review of the Documentation of Nursing Process and Care policy directed that the registered nurse will document an individualized

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patient care plan based on assessment within 24 hours of admission to a nursing unit, identify new patient problems and make changes in the plan of care based on ongoing assessment and change in status.
Review of the Suicide Precaution policy with the Risk Manager on 2/22/18 at 2:30 pm indicated that the policy provides guidelines for the management of patients at risk for suicide who require care in the behavioral health setting and is in the process of being revised. The policy directed that the team should initiate a plan of care with individualized precautions and interventions to ensure the patient's safety. The Risk Manager stated the hospital does not have a policy to address suicide precautions on the general nursing units.
Review of Patient #60's record reflected a physician's note dated 2/2/18 at 9:32 pm that identified the trauma team was informed that the patient was found with scissors in his/her possession. The note indicated that psychiatry was contacted and declined to place the patient back on one to one observation. Review of the nursing notes dated 2/5/18 at 10:41 am indicated that the physician team called the Nurse Manager to clarify an issue from 2/2/18. The note indicated that the patient was found with a suture removal kit and when asked, the patient stated he/she found the kit when cleaning the bedside table and gave it to the physical therapist (PT). Review of MD #100's note (psychiatrist) dated 2/5/18 reflected that the patient denied he/she had scissors and/or intended to use them and that the patient's overall compliance with treatment had improved. Interview with Nurse Manager #12 on 2/22/18 at 11:00 am stated she spoke with the physical therapist who corroborated the statement of the patient. Interview with MD #100 on 2/22/18 at 9:00 am stated he was aware of the incident and felt that the patient was not a danger to self. Review of the clinical record failed to reflect a note by the PT and/or RN on 2/2/18 describing the incident and/or a revision to the plan of care. The facility failed to have a policy and/or guidelines on reassessment of the patient after the initial suicide assessment completed on admission.
Review of the Documentation of Nursing Process and Care policy directed that the RN will reassess the patient every eight hours and as needed throughout the episodes of care.

Responses to #21:
1) Measures implemented to prevent a recurrence of each identified issue of noncompliance:
Safety Alert related to suicide risk was distributed via e-mail to all Nursing Leadership on 2/26/2018 for review with all staff and posted on the nursing units. Tip Sheet "Suicide risk/Ligature Risk-Required RN documentation for Patients on Suicide Precautions" distributed via e-mail to all Nursing Leadership on 2/28/2018, for review with RN staff and posted on all nursing units.

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Readiness Rallies for Leadership were conducted on 3/1/2018 and 5/11/2018 with review of policy requirements regarding suicide assessment and required documentation, development of an Interdisciplinary Plan of Care and reassessment of patient every 8 hours. Suicide Precautions Tip of the Month was distributed via e-mail in March 2018 to all Nursing Leadership for review with staff focused on assessment. Revision of Suicide Policy completed January 2018 including the reassessment of the patient every 8 hours. All staff completed Healthstream Ligature Risk: Assessing and Mitigating the Risk for Suicide by April 30th, 2018.
2) Date each such corrective measure or change is effective: please see dates above and below.
3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained. Audit of all patient care units was completed after each Readiness Rally (conducted on 3/1/2018 and 5/11/2018) to ensure suicide assessment and IPOC (Interdisciplinary Plan of Care) are completed.
4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Chief Nursing Officer.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or {c) Medical staff (2) and/or (e) Nursing service{]).

22.Based on clinical record review, facility documentation and interviews for one of three sampled Patients (Patient #13) reviewed for diabetes, the facility failed to ensure the clinical record addressed the patient's diabetic diagnosis. The findings include:

b. Patient (P) #13 was admitted for a cardiac catheterization procedure on 1/25/17, the patient's medical history included chronic back pain, osteoarthritis, hypertension, diabetes and anxiety. On 1/25/17, the patient underwent a cardiac catheterization procedure at 1:42PM and returned to the unit approximately 3:15 PM. Review of the physician's orders dated 1/25/17 at 3:19 PM directed a 2 gm Sodium/ low cholesterol diet.
Review of the patient's blood glucose point of care testing (POCT) results included the following: 1/25/17 at 10:51 AM-174 mg/dl (normal range 70-100 mg/dl), 3:04 PM-127 mg/dl, 8:14 PM-266 mg/dl, 1/26/17 at 9:31 AM-191, 2:29 PM-204, and 5:54 PM-173. A physician's order dated 1/26/17 directed sliding scale insulin coverage (Humalog 2-12 units based on glucose result) three times daily before meals. A physician's progress note dated 1/28/17 at 9:15 AM indicated that the patient's blood sugars have been running moderately elevated and noted that the patient was on sliding scale insulin coverage. Review of the clinical record failed to reflect that the prescribed diet addressed the patient's diabetic diagnosis and documented elevated glucose levels.
In an interview on 10/26/17 at 2:55 PM, Nurse Manager #11

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

identified there was no protocol for a diabetic patient following a cardiac stent procedure and that physician orders are followed. The Nurse Manager further identified if a sliding scale for insulin was ordered then the expectation is for POCT to be done and that a diabetic diet would be ordered but is not sure why this was not done.

Responses to #22:
1) Measures implemented to prevent a recurrence of each identified issue of noncompliance: E-mail sent to all providers in Medical Cardiology and CHF PA/NP on 5/15/2018 regarding the ordering of a consistent carbohydrate diet for all diabetic patients. E-mail sent to all Cardiologist on 5/15/2018 regarding the ordering of a consistent carbohydrate diet for all diabetic patients.
2) Date each such corrective measure or change is effective: please see dates above and below.
3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained. Monitor (starting May 16, 2018) 5 cases per week for 4 weeks to ensure correct diet is ordered for a diabetic patient.
4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Physician Chief, Cardiology.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (c) Medical staff (2) and/or (d) Medical Records (3).

23.Based on clinical record review and interview for I (P#199) of 5 patients reviewed for the u.se of restraints the hospital failed to ensure physician orders were timely according to hospital policy. The findings include:

c. Patient (P) #199 was evaluated in the Emergency Department (ED) on 1/22/17 and subsequently admitted for abdominal pain related to perforated diverticulitis. P#l99 was taken emergently to the operating room and then transferred to the surgical intensive care unit (SICU). P#l 99's postoperative course was complicated by severe agitation and delirium thought to be related to alcohol withdrawal.
According to the medical record a physician order for placement of bilateral soft wrist restraints on P#l99 was entered on 1/24/17 at 4:52 AM. A subsequent order to continue the use of the bilateral soft wrist restraints was entered on 1/25/17 at 6:10 AM, 25 hours and 18 minutes after the initial order.
On 1/26/17 at 5:59 PM a physician order for bilateral mitts was entered in the medical record. A subsequent order to continue the use of the bilateral mitts was entered on 1/28/17 at 3:06 AM, 33 hours and 5 minutes after the initial order.
The use of bilateral mitt restraints was discontinues on 1/29/17 at 3:17 AM. During a review of the medical record with the Vice President (VP) of Regulatory

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

Readiness on 12/12/17 at I :00 PM, he/she verified P#199's medical record was lacking documentation of a physician's order for non-behavioral medical restraints every 24 hours according to hospital policy.
Hospital Restraint policy indicated a physician/licensed independent practitioner order/renewal is required every 24 hours for the use of restraints for non-violent or non-self-destructive behavior.

Responses to #23:
1) Measures implemented to prevent a recurrence of each identified issue of noncompliance:
All staff assigned re-education on 8/29/17 via Healthstream related to restraint policy, including monitoring, documentation and proper orders.
2) Date each such corrective measure or change is effective: please see dates above and below.
3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained: Restraints audited weekly for 10 weeks from November 12, 2017 to January 20, 2018 to ensure that orders included the necessary requirements.
4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Chief Nursing Officer.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical staff(2) and/or (e) Nursing service (l) and/or (i) General (6) and/or (I) Infection control.

24.Based on clinical record review and interviews for I (P#58) of3 (P#49, P#50) patients reviewed who tested positive for tuberculosis the hospital failed to ensure the patient was placed in isolation timely according to hospital policy.
The findings include:

d. Patient (P) #58 had diagnoses that included heart failure and dementia. P#58 was admitted to the hospital for evaluation and treatment for an anterior ST elevation myocardial infarction (STEMI: heart attack) for which he/she underwent a left heart cardiac catheterization and stent placement on 2/8/17. On 2/10/17 P#58 exhibited blood tinged sputum. A chest X-ray dated 2/10/17 identified a right infiltrate or a mass/lesion. On 2/11/17 a CT-scan identified a large cavitary lesion in P#58's left upper lobe possibly an atypical infection like tuberculosis. A sputum culture was ordered and obtained on 2/11/17 at 7:06 PM. Preliminary sputum results dated 2/11/17 identified many acid fast bacilli (AFB: used to identify an active tuberculosis (TB) infection). Final sputum results dated 2/13/17 identified mycobacterium tuberculosis.
A pulmonary consult was obtained and a physician's order dated 2/13/14 indicated P#58 was to be placed on airborne isolation.

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

The Hospital Tuberculosis (TB) Control Plan policy indicated patients with suspected or known infectious TB should promptly be placed in isolation and treatment initiated. In addition the patient must be relocated to a negative pressure room.
During an interview with Infection Preventionist #1 and #2 on 11/7/17 at 10:30 AM they indicated that P#58 came in due to signs and symptoms of a STEMI (heart attack). P#58 did not exhibit symptoms of TB until 2/10/17 when he/she produced blood tinged sputum. They indicated on 2/10/17 P#58 should have been placed on air borne isolation in a negative pressure room however P#58 was not placed on isolation and moved to a negative pressure room until 2/13/17.

Responses to #24:
1) Measures implemented to prevent a recurrence of each identified issue of noncompliance:
100% of Unit 9-9 Registered Nurse Staff received and reviewed the Tuberculosis (TB) Control Plan by 12/31/2017. This review was documented as a read and sign, or electronically as a read receipt via email.
2) Date each such corrective measure or change is effective: please see dates enclosed.
3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained: An audit of all patients with suspected or confirmed TB admitted to 9-9 from December 1, 2017 to February 28, 2018 was conducted with 100% compliance to initiate airborne precautions.
4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Nursing Manager, 9-9

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (e) Nursing service (l) and/or (i) General (6) and/or (l) Infection control.

25.Based interviews and review of hospital policies for an employee (Registered Nurse #200) who tested positive for TB exposure the hospital failed to ensure the employee had received an annual evaluation of TB exposure as specified in the hospital policy. The findings include:

e. RN#200 was hired by the hospital on June 29, 2015 at which time a PPD test was performed and resulted in a negative reading.
A review of Occupational Health records with the Medical Director of Occupational Health on 11/7/l 7 at 11:45 failed to identify that RN#200 had received an annual evaluation of TB exposure in 2016 and should have.
Hospital policy for TB Control Plan identified all employees must receive an annual PPD test during their month of hire.

Responses to #25:

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

1) Measures implemented to prevent a recurrence of each identified issue of noncompliance: Each manager will run a HealthStream report at least monthly of their employees to ensure compliance with the annual PPD requirement according to the Hospital Tuberculosis Control Plan IC 5.3
2) Date each such corrective measure or change is effective: May 16, 2018.
3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained. Managers will report to their Directors any non-compliance with the Tuberculosis Control Plan IC 5.3 monthly, while following the procedures for compliance in the hospital plan under EMPLOYEE TUBERCULOSIS COUNSELING, SCREENING AND EVALUATION.
4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Directors of Departments

The following is a violation of the Regulation of Connecticut State Agencies
Section 19-13-D3 (j) General (6) and/or (l) Infection control.

26.Based on clinical record review and interviews for 1 (P#9) of 3 patients that underwent a surgical procedure the hospital failed to ensure the patient did not develop an infection. The findings include:

f. Patient (P) #9 was admitted to the hospital for surgical revision of his/her total left shoulder replacement on 5/12/16. Diagnoses included osteoarthritis, asthma, chronic bronchitis and Diabetes Mellitus, type II.
Signed consent indicated complications and risks involved with a shoulder replacement included, nerve damage, infection, stiffness or laxity of the joint and continued pain postoperatively. In addition diabetic patients are at increased risk for superficial and deep infection.
The Operative Note (OP) by Medical Doctor (MD) #19 indicated P#9's left upper extremity was scrubbed, prepped and draped. The note indicated during the procedure the joint fluid appeared clear and no signs of infection were encountered. The wound was thoroughly "pulse vac'd" and lavaged twice and upon completion of the procedure the skin was closed in layers and a sterile dressing was applied. A discharge summary dated 5/14/16 indicated P#9 received perioperative antibiotic prophylaxis for infection prevention.
Subsequently on 6/5/16 P#9 was evaluated in the ED and admitted due to new onset pain, swelling and drainage from his/her left shoulder replacement incision. An ED admission note indicated P#9's presentation was concerning for a surgical wound infection with prosthetic hardware. P#9's vital signs were stable and he/she did not show signs and symptoms of sepsis. Initial wound cultures identified Methicillin resistant staph aureus (MRSA). An OP note dated 6/7/16 indicated P#9 was taken to the operating room, due to an infected left shoulder, for irrigation, debridement and removal of prosthetic hardware.

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During an interview with MD#24 (Infectious Disease) on 11/8/17 at 11:30 AM he/she indicated because P#9 had developed an infection within 1 month of having surgery the infection was considered an early peri-prosthetic joint infection (PJI). In most cases PH's exposure occurs during surgery or postoperatively when a wound dehisces (wound ruptures along a surgical incision).

Responses to #26:
1) Measures implemented to prevent a recurrence of each identified issue of noncompliance:
Clarification: Patient #9's chart was reviewed in November 2017 by the Executive Director of the Orthopedic Service Line and the patient received all appropriate precautionary treatments for prevention of infection for a revision of a total joint arthroplasty case. Infection is a known risk of total joint arthroplasty (TJA) and slightly higher risk for revision of TJA. The patient did sign informed consent acknowledging this was a risk for surgery. The national benchmark for periprosthetic joint infection (PJI) rate following shoulder arthroplasty is 4%, with revision having an overall higher rate. In 2016, the PJI rate following shoulder arthroplasty at CJRI was 0.83% for all cases. The shoulder rate since that time at CJRI is 0.81%
2) Date each such corrective measure or change is effective: November 2017.
3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained: All adverse outcomes including PJI are reviewed in detail by the Musculoskeletal Outcomes Team including risk analysis, protocol compliance, and statistical processing to search for statistically and clinically significant increases in complication rates. Each surgeon is provided a monthly report outlining complications, and benchmark across all surgeons at CJRI. Select cases are discussed at bimonthly healthcare value advisory council meetings for which all surgeons are encouraged to attend.
4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Executive Director, Orthopedic Service Line

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (c) Medical staff (2).

27.*Based on clinical record review and interview for 1 (P#43) of 4 patients who required central line insertion the hospital failed to ensure correct placement (venous) and/or maintain the central line according to hospital policy. The findings include:

g. Patient (P) #43 was evaluated in the Emergency Department (ED) on 9/8/16 for complaints of increased fatigue, confusion and difficulty

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

breathing. Past medical history included diabetes mellitus, hypertension, perforated diverticulitis, colon resection with ostomy and invasive micro discectomy of the lumbar spine, obstructive sleep apnea, obesity and chronic obstructive pulmonary disease (COPD) requiring oxygen. While in the ED P#43 was placed on BiPap (noninvasive ventilation) and became more confused requiring intubation. P#43 was identified as critical with respiratory failure and shock requiring the placement of a triple lumen central venous catheter (CVC: triple lumen) in the right subclavian.

According to a progress note by Medical Doctor (MD) #20 dated 9/8/16 at 4:19 PM the CVC was assessed to have blood return through all ports, free fluid flow and a chest X-ray verified the right tip of the catheter over the region of the superior vena cava or left/right brachiocephalic vein across midline. The CXR indicated during the X-ray P#43's position was significantly rotated.

A nursing assessment dated 9/8/16 at 3:00 PM indicated the subclavian CVC had positive blood return however did not differentiate which lumen of the triple lumen catheter produced a blood return. Subsequent nursing assessments dated 9/8/16 through 9/11/16 indicated the CVC line was "infusing" however the documentation failed to identify the flushing and/or blood return of each of the lumens.

Hospital Central Venous Access Devices, Guidelines, dated March 2015, references the use of Lippincott Central Venous Access Devices Flushing and Locking for management of the CVC. Lippincott indicated aspirating for a blood return and flushing all lumens of a multi lumen catheter is a routine step to assess catheter patency. Documentation should include patency of the catheter, presence of a blood return and lack of resistance when flushing.

During an review of the medical record with Safety and Regulatory Compliance Specialist #1 on I 1/7/17 at 2:35 PM he/she indicated the nursing documentation did indicate the line was infusing however did not identify an assessment of all lumens.

A nurse's note dated 9/11/16 at 4:30 AM indicated during an attempt to draw blood off the right subclavian triple lumen catheter, blood appeared to be bright red and pressurized. The line was transduced and arterial wave form was noted on the monitor. An arterial blood gas (ABG) was ordered, drawn and the CVC blood was confirmed to be arterial not venous.

P#43 was taken to the Operating Room (OR) for removal of the CVC. Subsequently post operatively no ill effects from the CVC placement and removal werenoted.

During an interview with MD#20 on 11/7/17 at 2:45 PM, MD#20

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indicated "if the CVC was in the right subclavian artery on day 3 (9/11/16) then it was in the artery on day I (9/8/17)". MD#20 indicated the placement was verified on X-ray which could be difficult due to the patient's size and position (rotation). In addition the blood return was not bright red and/or pulsatile, indicating arterial, because the patient was hypovolemic at the time.

P#43 progressed and was transferred to a step down unit on 9/23/16, a monitored unit on 9/26/17 and discharged to an extended care facility (ECF) on 10/1/16.

Responses to #27:

1) Measures implemented to prevent a recurrence of each identified issue of noncompliance:

Hospital wide nursing re-education, initiated on 10/1/16 and completed by 10/29/16 via a read and sign, including nursing and physician leadership , regarding signs of issues/concerns with CVCs, escalation of those concerns, and clarification with the provider that a newly placed CVC is cleared for use. CMO/CQO discussed at MEC 11-8-16. Discussed at Quality Committee October 2016.

Clarification: Care reflected attention per standards for insertion of central lines. Proper technique, by experienced provider was used for CVC insertion. The site for insertion, subclavian placement, was chosen due to patient anatomy and the critically of the situation. Patient was sedated and intubated- both of which prevented movement during insertion of the central line. Post procedure CXR performed to verify correct placement of the central line.

2) Date each such corrective measure or change is effective: 10/29/2016.

3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained. All unanticipated outcomes are reviewed at the Serious Safety Event Committee. Line placement audit December 2016 - Feb. 2017

4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Directors of Nursing.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 {d) Medical records {3) and/or {e) Nursing Services {l).

28.Based on clinical record review and interview for I (P#6) of 3 (P#53, P#54) patients reviewed who underwent a colonoscopy/endoscopy the hospital failed to ensure a postoperative nursing assessment was complete prior to discharge. The findings include:

h. Patient (P) #6 underwent a colonoscopy/endoscopy on 10/27/16 at 10:21 AM for evaluation of generalized abdominal pain and difficulty swallowing. P#6's history included gastroesophageal reflux disease (GERD), unspecified abdominal pain, chronic ovarian papillary adenocarcinoma, congestive heart failure and renal insufficiency.

An anesthesia postoperative assessment dated 10/27/16 at 12:38 PM indicated P#6 had experienced no anesthetic complications. He/she was awake, alert, oriented with unassisted respiratory support and stable vital signs and hydration. The assessment indicated P#6 had

TTHE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

adequate postoperative pain control.Procedure notes dated 10/27/16 at 12:41 PM by Medical Doctor (MD) #22 indicated both the endoscopy and colonoscopy were accomplished without difficulty and P#6 tolerated the procedures well with no immediate complications identified.

Review of the medical record with Safety and Regulatory Compliance Specialist #1 on 11/2/17 at 2:40 PM identified that although postoperative assessments were completed by the MD and anesthesia the medical record lacked documentation by a registered nurse (RN) of P#6's gastrointestinal (GI) assessment and pain assessment prior to discharge and should have based on nursing/facility practice.
Responses to #28:
1) Measures implemented to prevent a recurrence of each identified issue of noncompliance:
On November 8, 2017 the Manager of the Endoscopy Department Safety Huddle reviewed the documentation requirement of the post procedure nursing assessments with staff. At the November 16, 2017 Endoscopy Department staff meeting, the manager discussed the DPH finding of a lack of documentation of a post procedure nursing GI assessment and pain assessment prior to discharge. The post procedure care and recovery guidelines policy was sent via email to all RN Endoscopy staff on November 20, 2017 as a read and sign.
2) Date each such corrective measure or change is effective: see above dates.
3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained. Random, unannounced weekly audits were conducted from December 5, 2017 through February 28, 2018 to identify compliance with documentation of post procedure assessments.
4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Manager of Endoscopy

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing service (2), and/or (i) General (6).

29.Based on clinical record reviews, review of policies and procedures and interviews with facility personnel for one of three sampled patients (Patient #62), the facility failed to ensure that the Richmond Agitation Sedation Scale (RASS) was assessed with a change in titration of a sedative. The findings include:

i. Patient #62 was admitted to the hospital on 10/21/17 with sepsis. Review of the physician orders dated 10/30/17 identified that the patient was to receive Propofol IV- titrate to protocol. Review of the clinical record dated 10/30/17-10/31/17 identified that on 10/30/17 at 5:06pm, the dose of the Propofol IV was changed to 30 mcg/kg/min and on I 0/31/17 at 3:O0am the dose was changed to 20 mcg/kg/min. Further review failed to identify that an assessment of the RASS scale

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was conducted with the change in titration. Interview with the Assistant Nurse Manager on 10/31/17 identified that the RASS scale needed to be assessed with any change in titration. Review of hospital policy identified to document the level of sedation using RASS scale every four hours and whenever titration is needed.

Responses to #29:

1) Measures implemented to prevent a recurrence of each identified issue of noncompliance: On October 23, 2017, all MSICU staff RNs received by email a read and sign SBAR identifying the need for a specific order for Propofol (not per protocol) and the need for RNs to document the Propofol titrations which correspond with the nursing assessment/documentation of RASS in all patients receiving Propofol.
2) Date each such corrective measure or change is effective: please see dates above and below.
3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained. Starting November 18, 2017, weekly audits of 5 charts were conducted by the Assistant Nurse Manager for 10 weeks for compliance with documentation of Propofol titrations and assessment/documentation of RASS in patients receiving Propofol.
4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Assistant Nurse Manager, MSICU

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical staff (2)(B) and/or (d) Medical Records (3).

30.Based on a review of clinical records, staff interviews and a review of hospital policies, for one of two sampled patients' who received Magnesium Sulfate (Patient #39), the facility failed to monitor vital signs in accordance with the hospital policy. The finding included:

j. Patient #39 was admitted to the hospital on 10/19/17 at thirty-eight weeks and 3 days gestation for induction of labor. A physician's order dated 10/20/17 at 9:32 pm directed a Magnesium Sulfate 4 gram bolus intravenously (N) then 2 grams per hour. Review of the medication administration record dated 10/20/17 identified that the patient received a 4 gram loading dose of Magnesium Sulfate IV at 9:55 pm and 2 gram/hour started at 10:25 pm. Review of the clinical record dated 10/20/17 during the period of 9:55 pm through 12:02 am (10/21/17) identified that vital signs were obtained at 9:55 pm,

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

10:27 pm, 11:11 pm, and 12:02 am. Interviews with the Nurse Manager and Nurse Educator on 10/24/17 at 10:30 am identified that vital signs were not obtained with the frequency as directed by the hospital's policy. Review of the Magnesium Sulfate policy directed to obtain a baseline BUN/Cr prior to or upon initiation of magnesium sulfate (within six hours prior to initiation). During the loading dose, assess vital signs (BP, RR, HR, and oxygen saturation) every five minutes. Ongoing assessments include vital signs every fifteen minutes for the first hour, every 30 minutes during the second hour, then hourly.

Responses to #30:

1) Measures implemented to prevent a recurrence of each identified issue of noncompliance: The requirement to monitor vital signs in accordance with hospital policy was discussed at daily Safety Huddles the weeks of November 21 and 28, 2017. A quick assessment guide was created for all staff on 11/22/17 and distributed on November 27, 2017 through email for read and sign with completion on December 1, 2017.

2) Date each such corrective measure or change is effective: please see dates above and below.

3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained. Weekly audits of 5 charts were conducted by the Charge Nurses for 10 weeks for compliance with documentation of vital signs of patients receiving Magnesium Sulfate.

4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Executive Director, Women and Infants.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (d) Medical records (3) and/or (e) Nursing Services (1).

31.Based on a review of clinical records, interviews, and policy review, for one of two patients' that required epidural analgesia (Patient #37), the hospital failed to ensure that the patient's vital signs were monitored in accordance with the hospital's policy. The finding includes the following:

k. Patient #37 was admitted to the hospital on 10/23/17 at 39 weeks and 4 days gestation to rule of labor. A physician's order dated 10/23/17 at 6:13 am directed a continuous epidural infusion. Review of the Anesthesia record dated 10/23/17 identified that the patient had an epidural catheter inserted for pain management at 6:14 am with a test dose at 6:33 am followed by a continuous infusion. Review of the clinical record during the period of 6:33 am through 7:30 am indicated that vital signs were obtained at 6:33 am, 6:36 am, 6:39 am, 6:41 am

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

(no blood pressure), 6:43 am (no blood pressure), 6:57 Dam, and 7:30 am. Record review and interviews with the Nurse Manager and Nurse Educator on 10/24/17 at 11 am identified that vital signs were not obtained in a comprehensive manner and/or with the frequency as directed by the hospital's practice guidelines. Review of the Epidural Anesthesia Practice Guidelines during labor directed to assess vital signs (BP, RR, HR, and oxygen saturation) every 3 minutes for 20 minutes following test dose. Document on epidural flowsheet at start of continuous infusion with every ½ hour X 2 then hourly until infusion is discontinued.

Responses to #31:

1) Measures implemented to prevent a recurrence of each identified issue of noncompliance: The requirement to monitor vital signs in accordance with hospital policy was discussed at daily Safety Huddles the weeks of November 21 and 28, 2017. A quick assessment guide was created for all staff on 11/22/17 and distributed on November 27, 2017 through email for read and sign with completion on December 1, 2017.
2) Date each such corrective measure or change is effective: please see dates above and below.
3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained. Weekly audits of 5 charts were conducted by the Charge Nurses for 10 weeks for compliance with documentation of vital signs of patients with epidural analgesia.
4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Executive Director, Women and Infants.

32.Based on observations, interview of hospital staff, an interview of the Chairman of the Radiation Safety Committee and a review of documents pertinent to the radiation protection program, the hospital failed to ensure compliance with radiation regulations. Within the inspection the following violations were noted:

1. Sec. 19-24-5. Maximum doses
(a)(l) requires in part that operations are conducted in such a manner that occupational employees are not exposed to a lens of eye dose greater than 1-1/4 Rem per calendar quarter.

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

Contrary to the above, St. Francis Hospital had an individual over the past three years that received a lens of eye dose greater than 1-1/4 Rem per calendar quarter.

m. Section 19-24-8 "Radiation Information Labeling" states: Each area or room in which sources of ionizing radiation other than radioactive materials are used shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and appropriate wording to designate the nature of the source or sources of ionizing radiation (example below)

CAUTION* X-RAY

Additionally, section 19-24-8 also states: CAUTION* RADIATION AREA

This provision shall not apply to areas or rooms where x-ray equipment is used solely for diagnostic purposes by or under the direction of a healing arts practitioner as authorized by law"

Contrary to this, all rooms which utilized X-Ray devices and that were inspected were posted "Caution Radiation Area"

Additionally, not all access portals to areas containing X-Ray devices were posted.

a. Section 19-24-9 "Shipment in Compliance with Federal Regulations"

Contrary to this after a review of documents it was determined that not all staff who were involved in the transportation process of radioactive material had received 49 CFR Part 172 Subpart H Training for Hazmat Employees.

Responses to #32.a:

1) Measures implemented to prevent a recurrence of each identified issue of noncompliance:

Nature of the Incident: During the 3rd quarter of 2017, a cardiology physician received a lens of the eye dose of 1.49 Rem which exceeds the CT limit of 1.25 Rem. The majority of this dose, 1.17 Rem, occurred during the month of September, 2017.

St Francis monitors exposures on a monthly basis. Note that the exposure investigation and the proposed corrective actions were completed in early October 2017, prior to the CT inspection. The St Francis Radiation Safety Office was notified of the elevated exposure by our monitoring service. The St Francis Radiation Safety Officer (RSO) reviewed the exposure and conducted an investigation into the root cause. The exposure and investigation were reviewed by the St Francis Radiation Safety Committee (RSC) during the November 15, 2017 meeting. The affected

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Cardiologist has been consulted on self-protection measures by the Cardiology representative on the RSC. The proposed corrective actions were approved by the RSC during the November 15, 2017 meeting and completed by the end of that day.
2) Date each such corrective measure or change is effective: see above dates.
3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained. The RSC will review the affected cardiologist's dosimetry during each meeting for the next four quarters. The St Francis dosimetry monitoring service is set to notify the Radiation Safety Office when any whole body dosimeter exceeds a quarterly action level of 0.375 Rem.
4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: The RSO is responsible for presenting dosimetry to the RSC and reviewing elevated exposure alerts from the dosimetry service. The RSC will be responsible for reviewing the data and effectiveness of the corrective actions.

Responses to #32.b:
1) Measures implemented to prevent a recurrence of each identified issue of noncompliance: Signs bearing the radiation caution symbol and "CAUTION X-RAY" were placed on each door into any room where x-ray equipment is used by the end of the day when they were identified in October, 2017.
2) Date each such corrective measure or change is effective: see above.
3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained. A review of x-ray signage will be included in the RSO's annual review of the facility's Radiation Protection Program.
4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: The RSO will be responsible for ensuring the corrective actions are implemented.

Responses to #32.c:
1) Measures implemented to prevent a recurrence of each identified issue of noncompliance:
Radioactive Materials Shipping was completed for each Hazmat employee in accordance with 49CFR172.
Initial Hazmat Training has been added to the list of required initial training for all new employees who will be designated as Hazmat employees. The RSO will be responsible for providing testing, administering exams, and signing training certificates to all Hazmat employees. The Nuclear Medicine supervisor and Oncology supervisor will be responsible for referring all new employees to the RSO for testing. A review of Hazmat Training records has been added as an audit item to

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

the RSO's annual review of the facility's Radiation Protection Program.

Corrective Action Timeline: All Hazmat employees completed Hazmat Training by December 22, 2017.
2) Date each such corrective measure or change is effective: see dates above.
3) Plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained: A review of Hazmat Training records has been added as an audit item to the RSO's annual review of the facility's Radiation Protection Program.
4) Title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction: Radiation Safety Officer.